

T02F90" 60908860

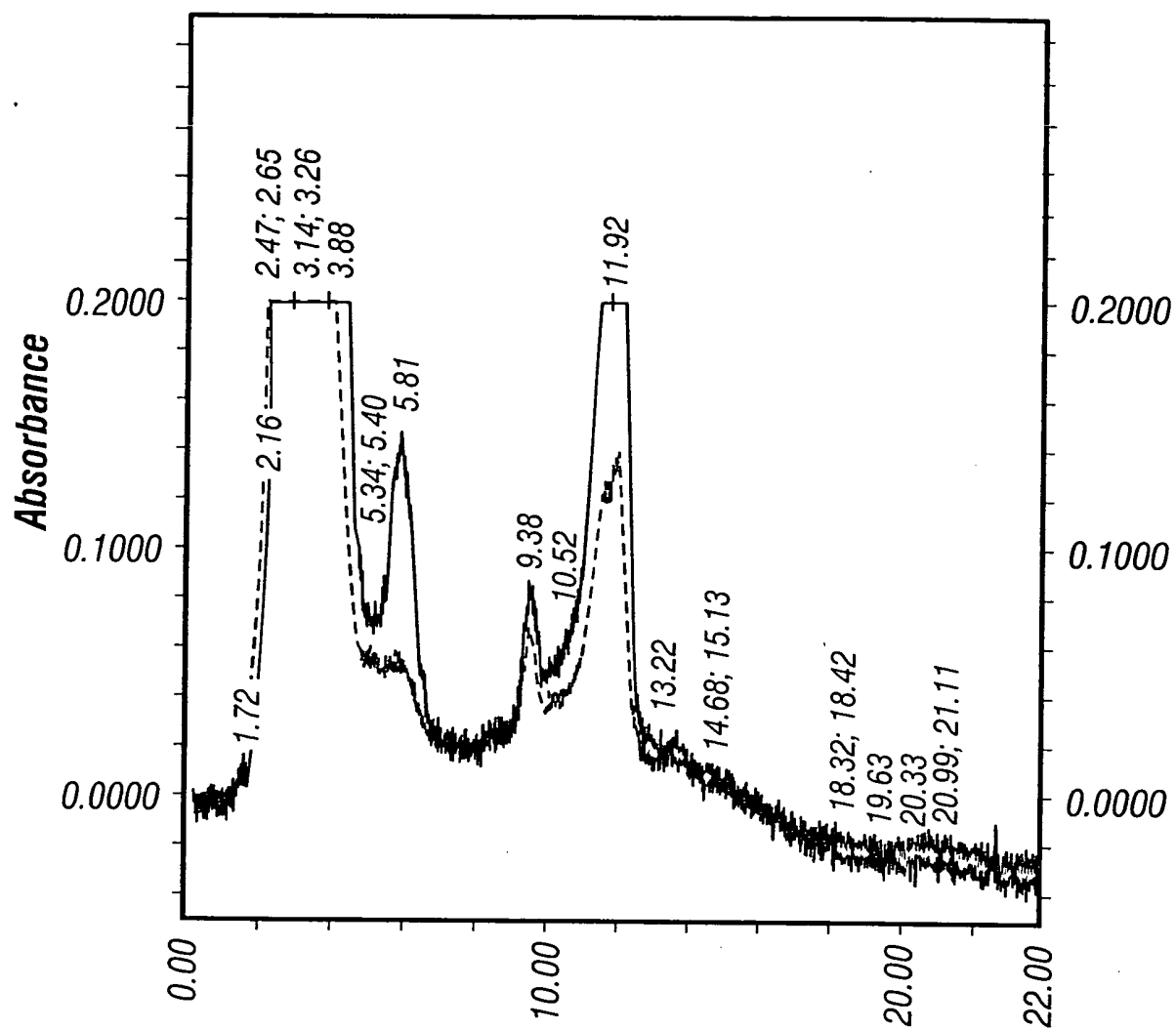


FIG. 1A

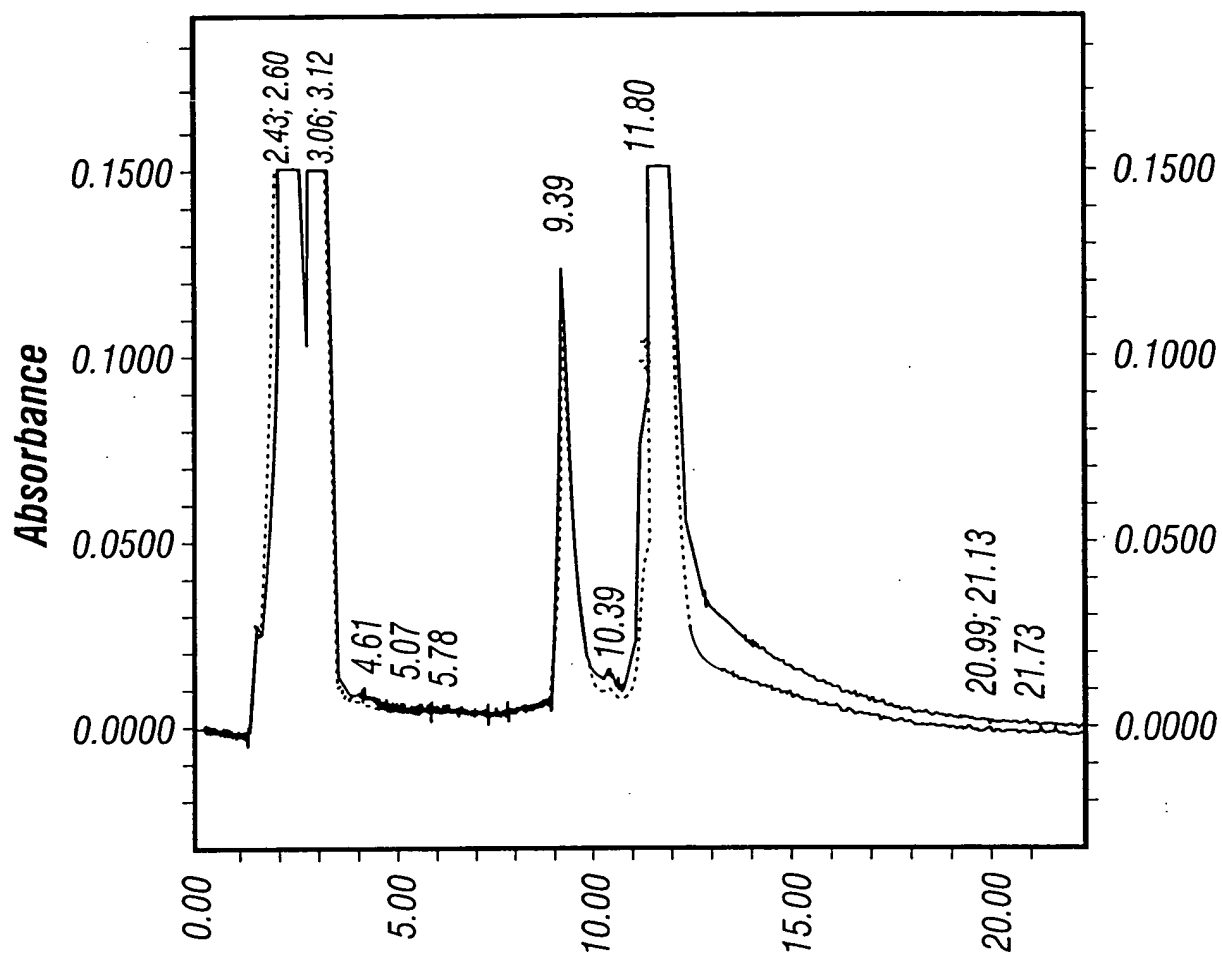


FIG. 1B

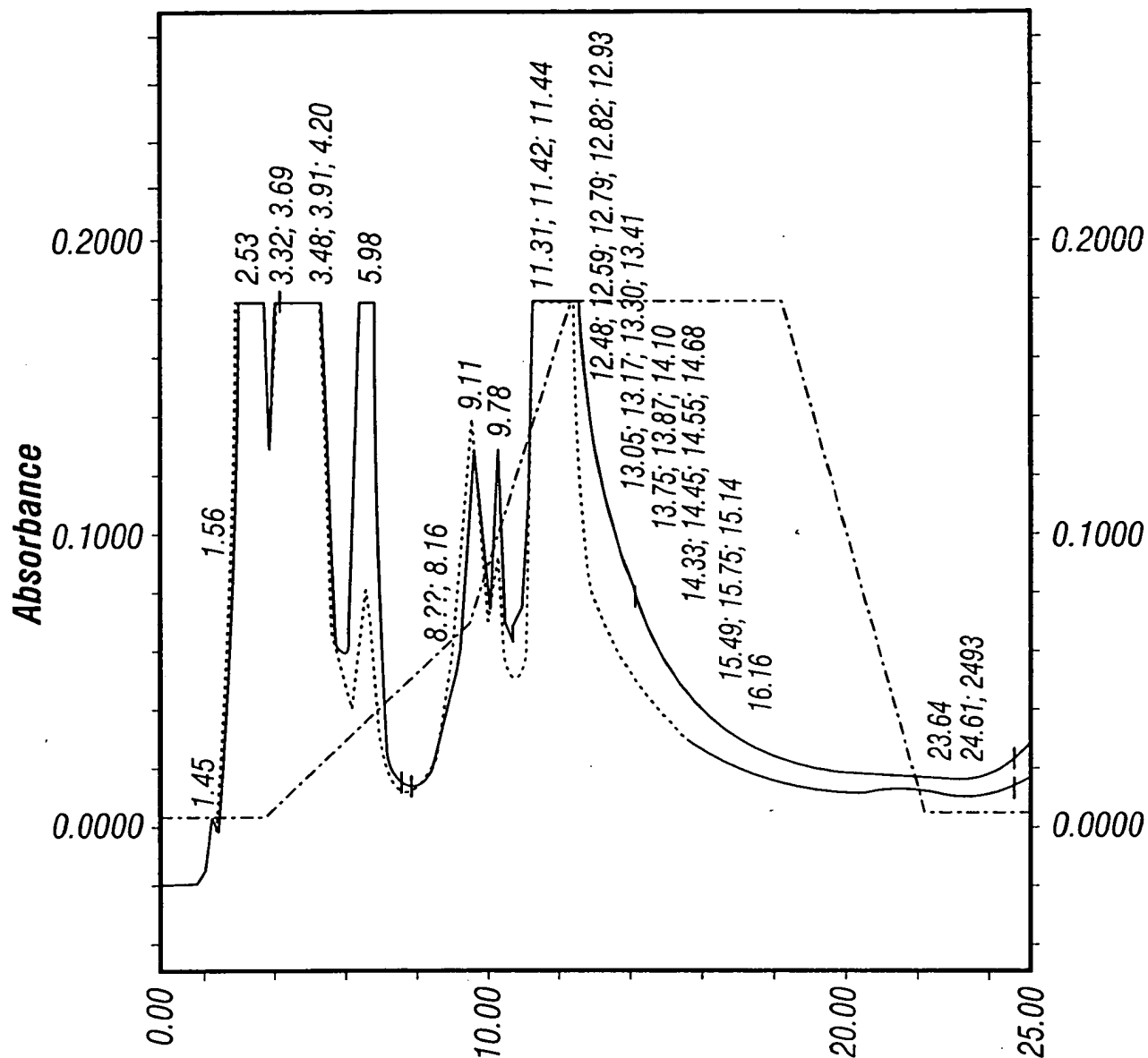


FIG. 2

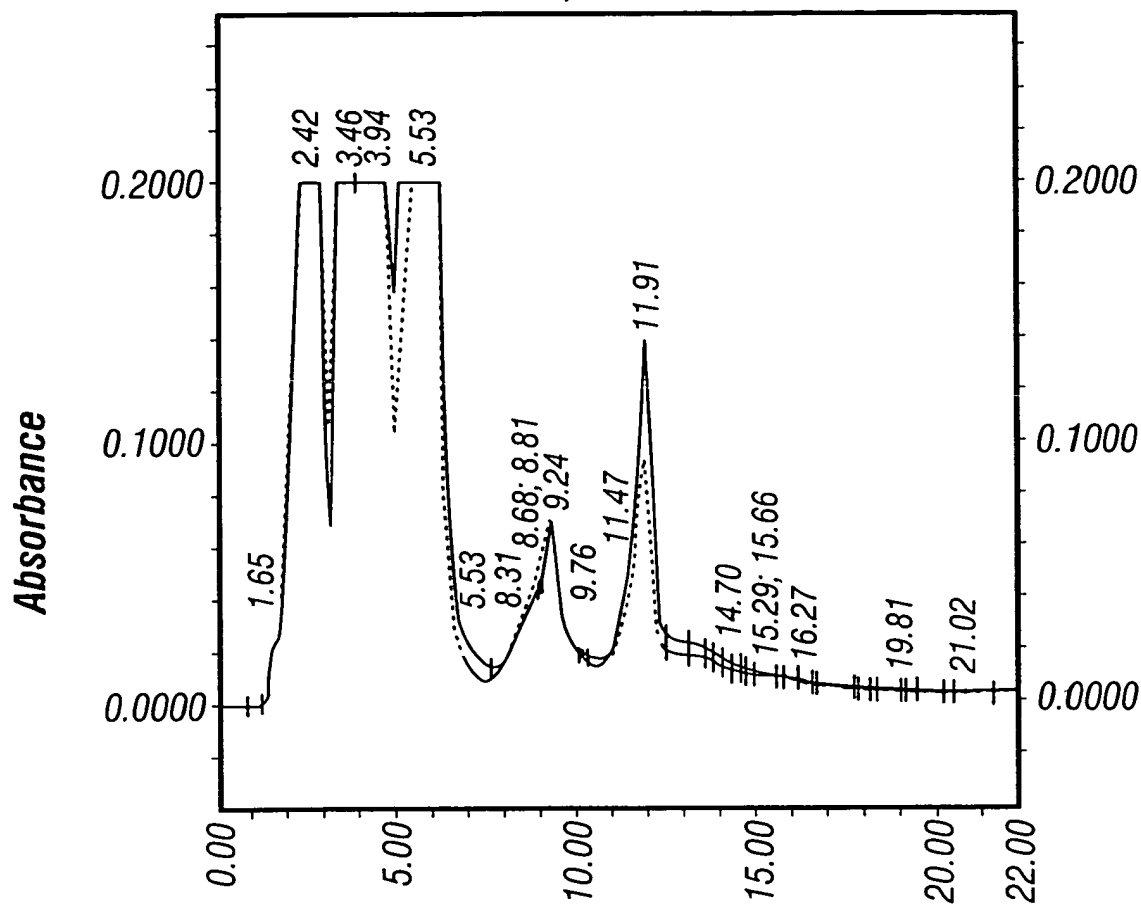


FIG. 3A

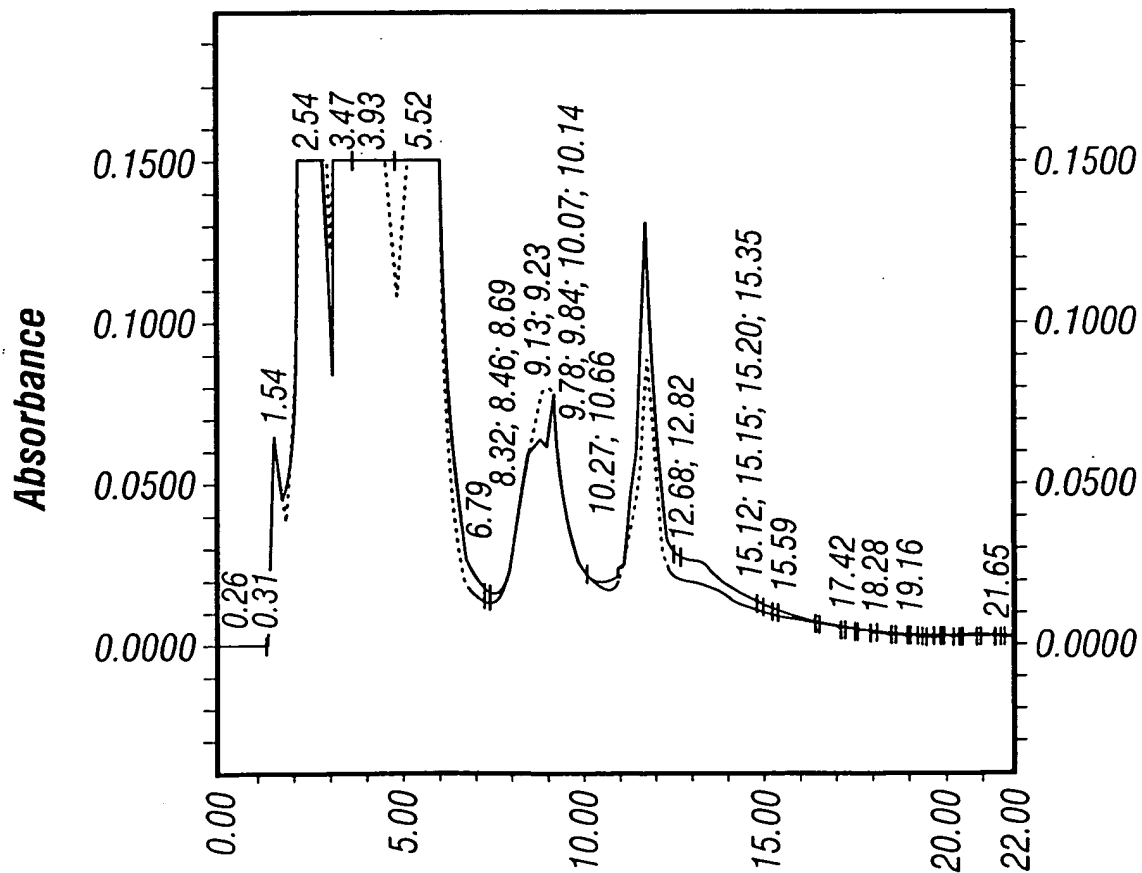


FIG. 3B

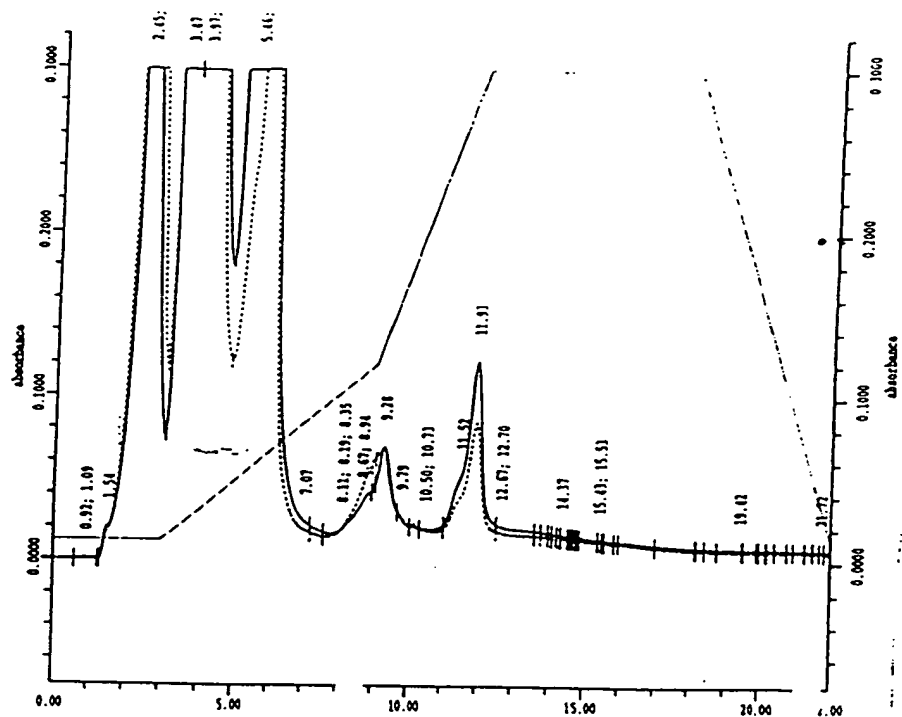


FIG.3C

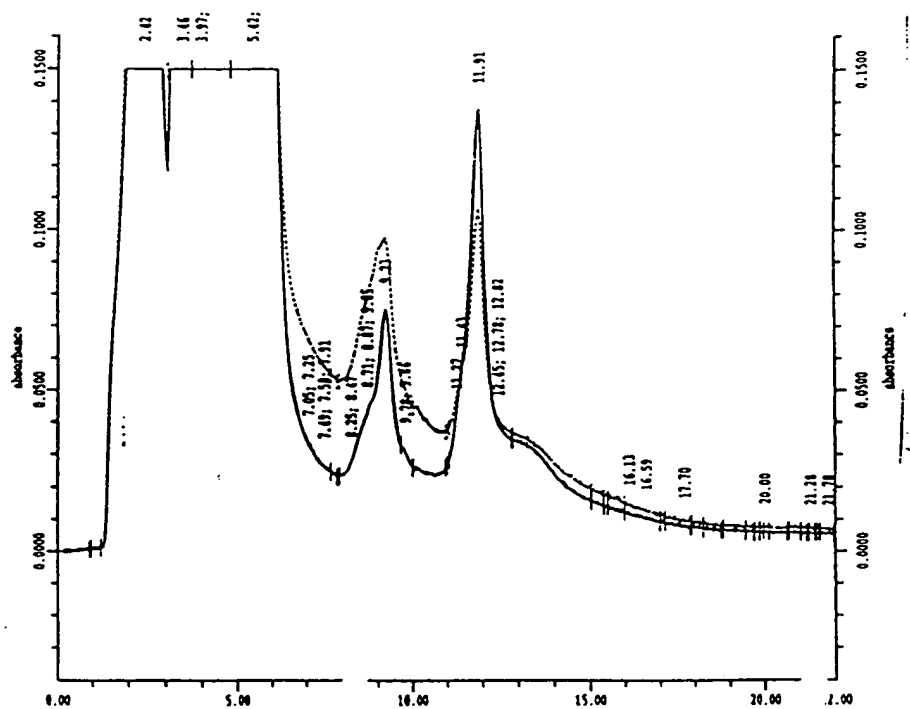


FIG.3D

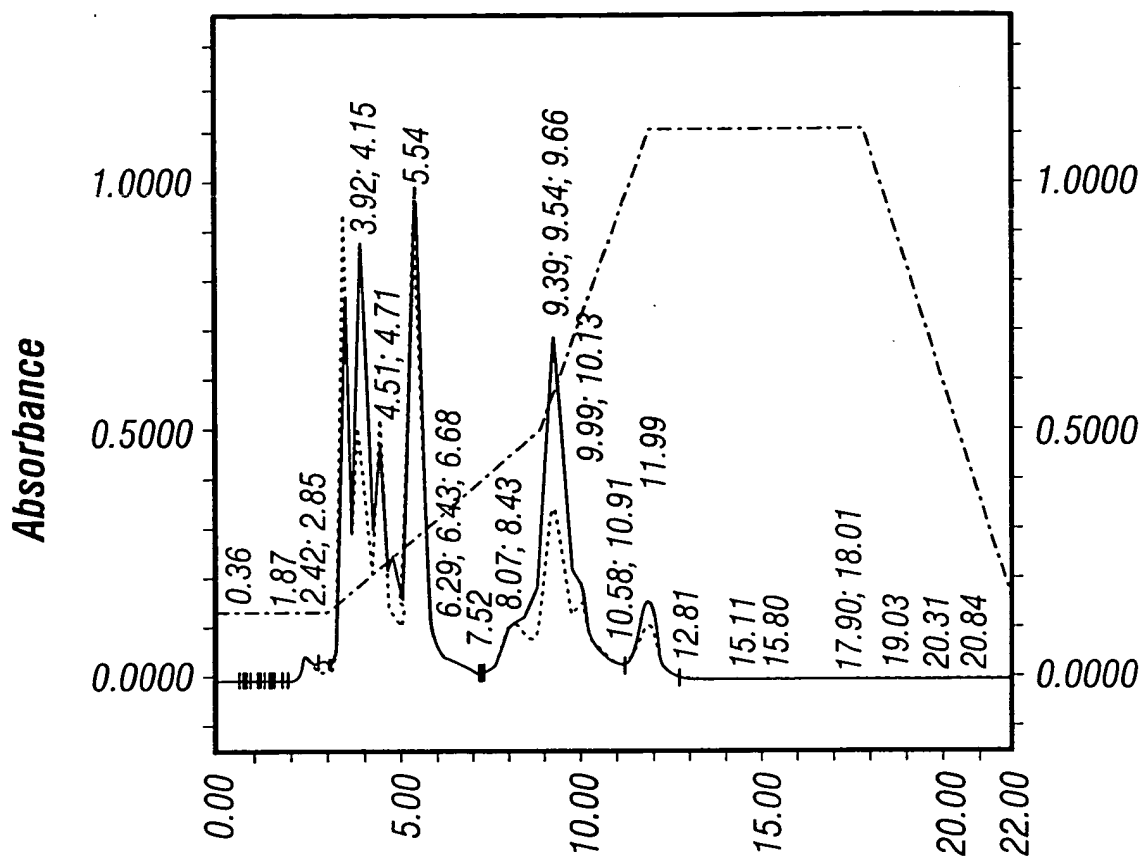
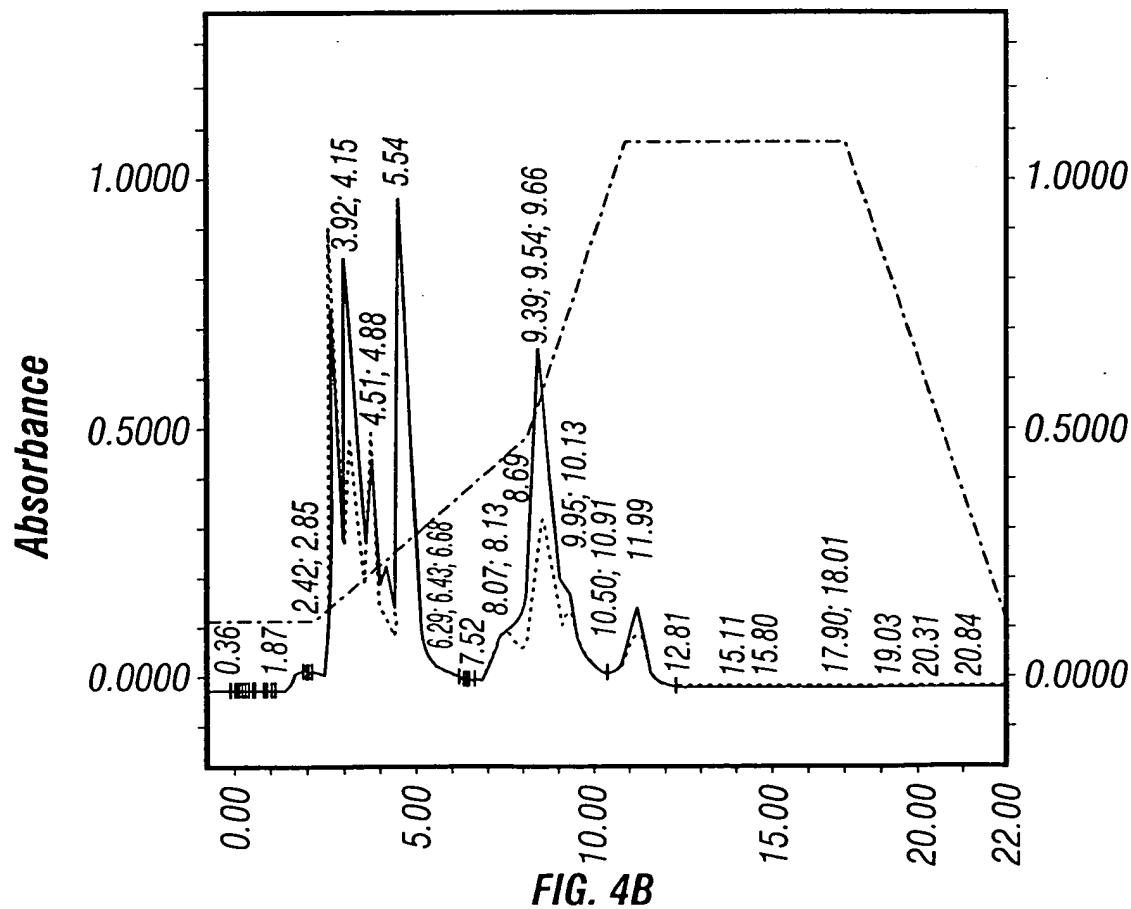
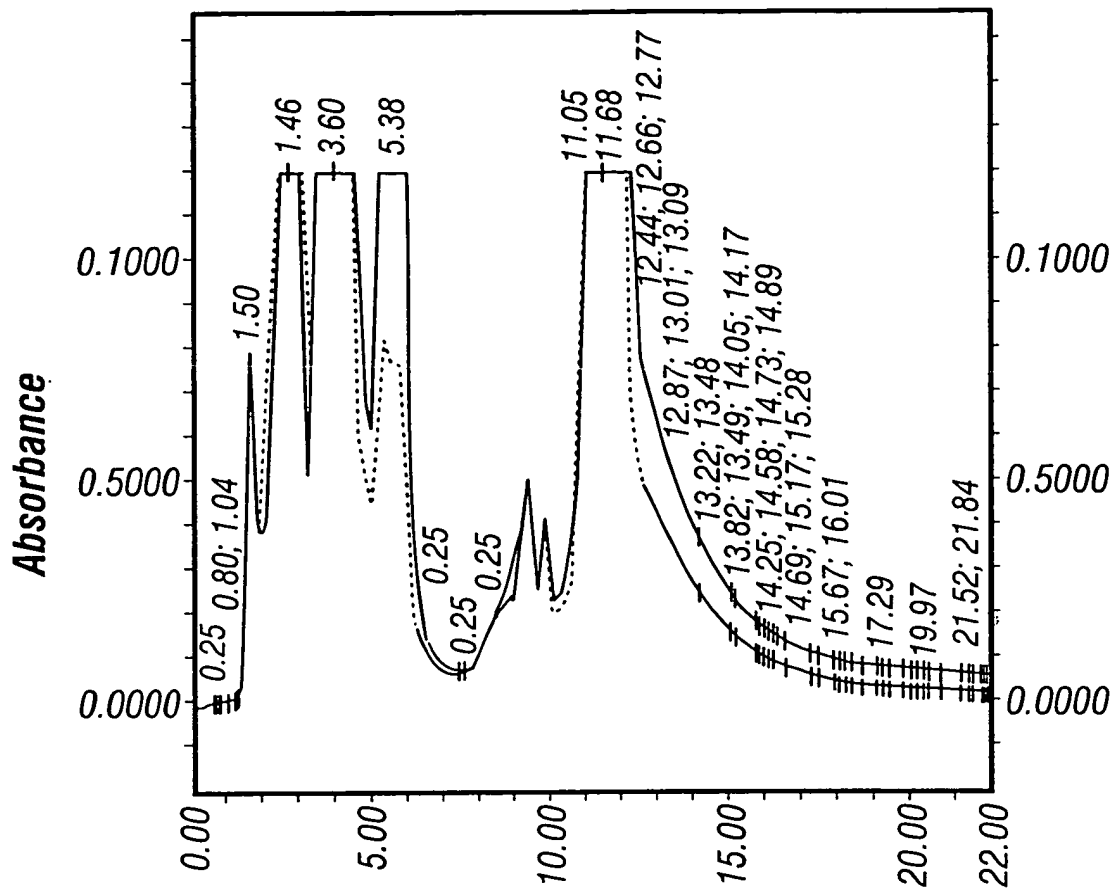


FIG. 3E



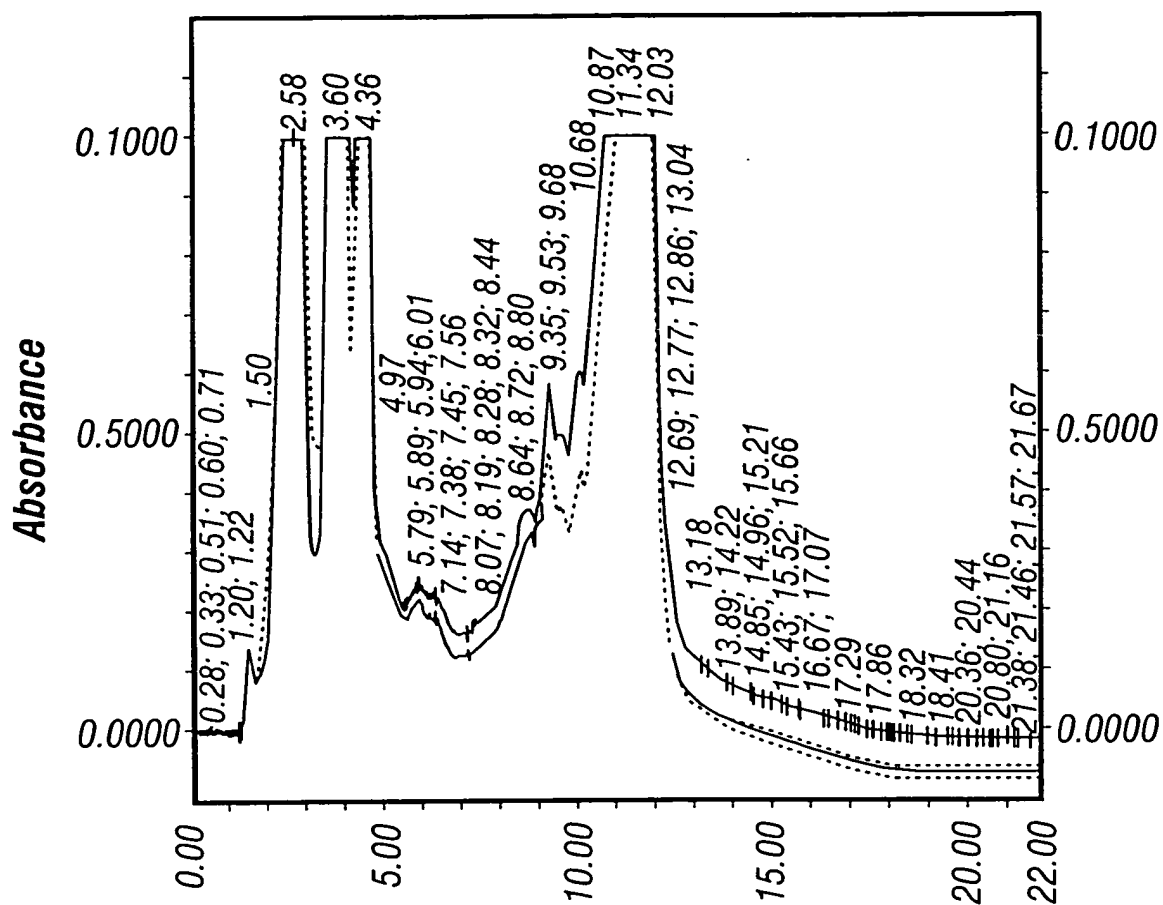


FIG. 5

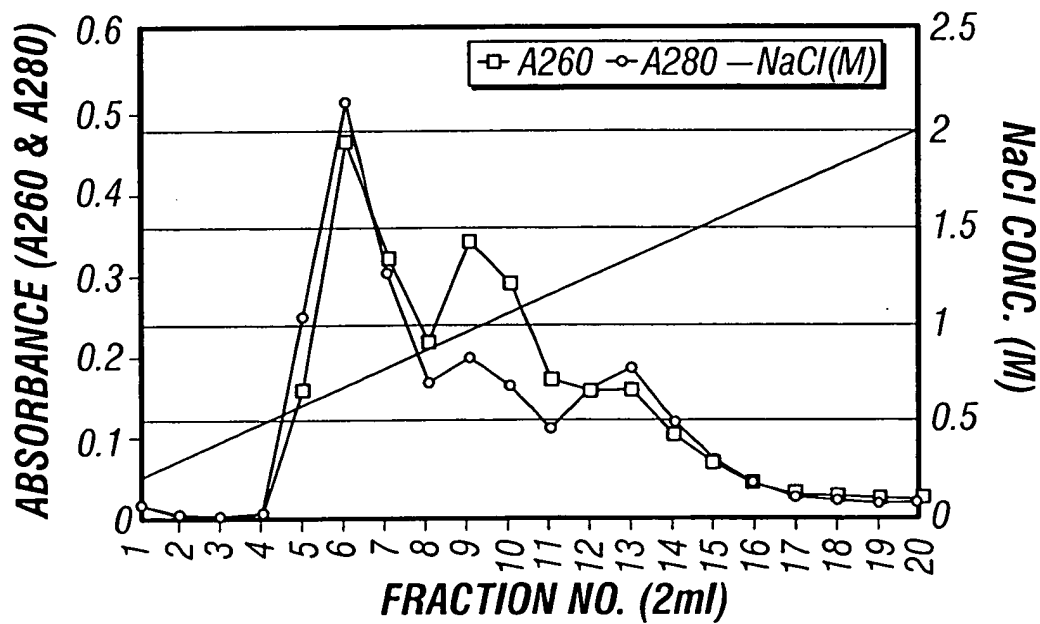


FIG. 6



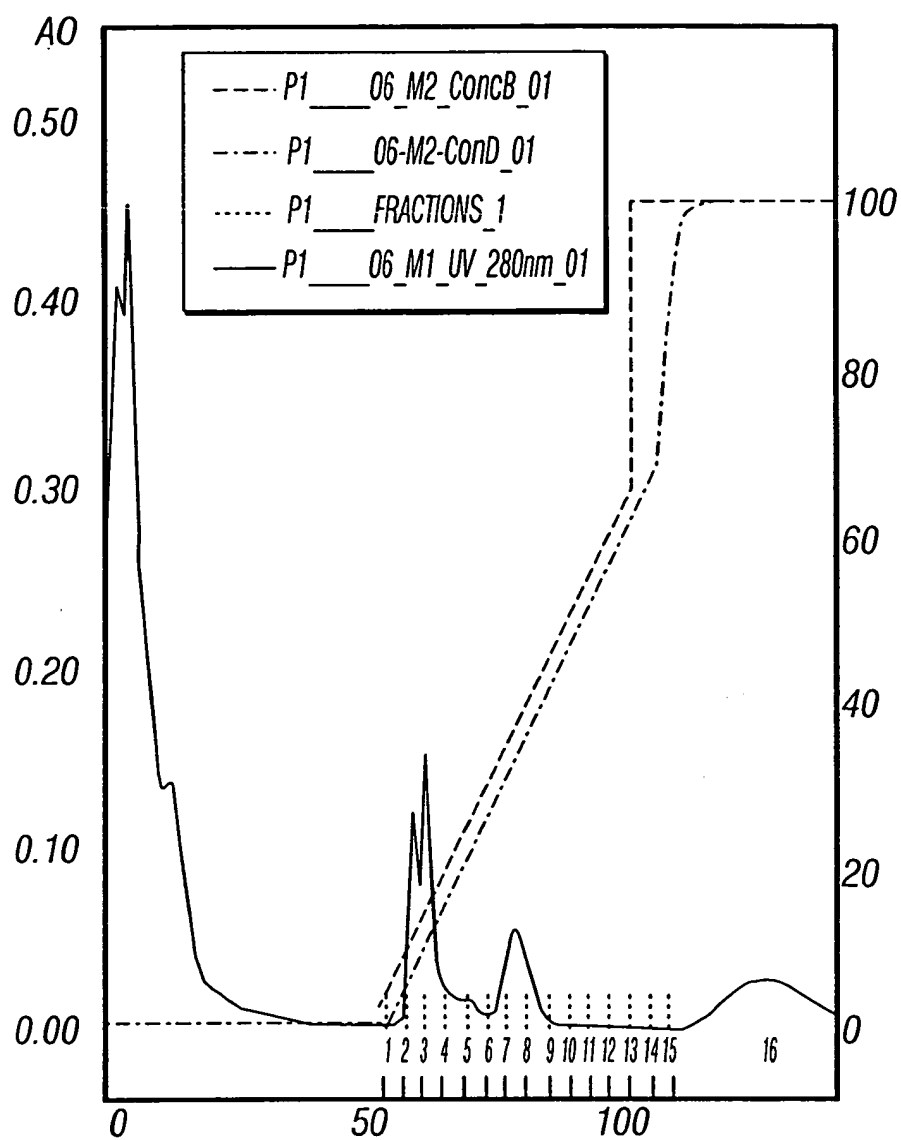


FIG. 7

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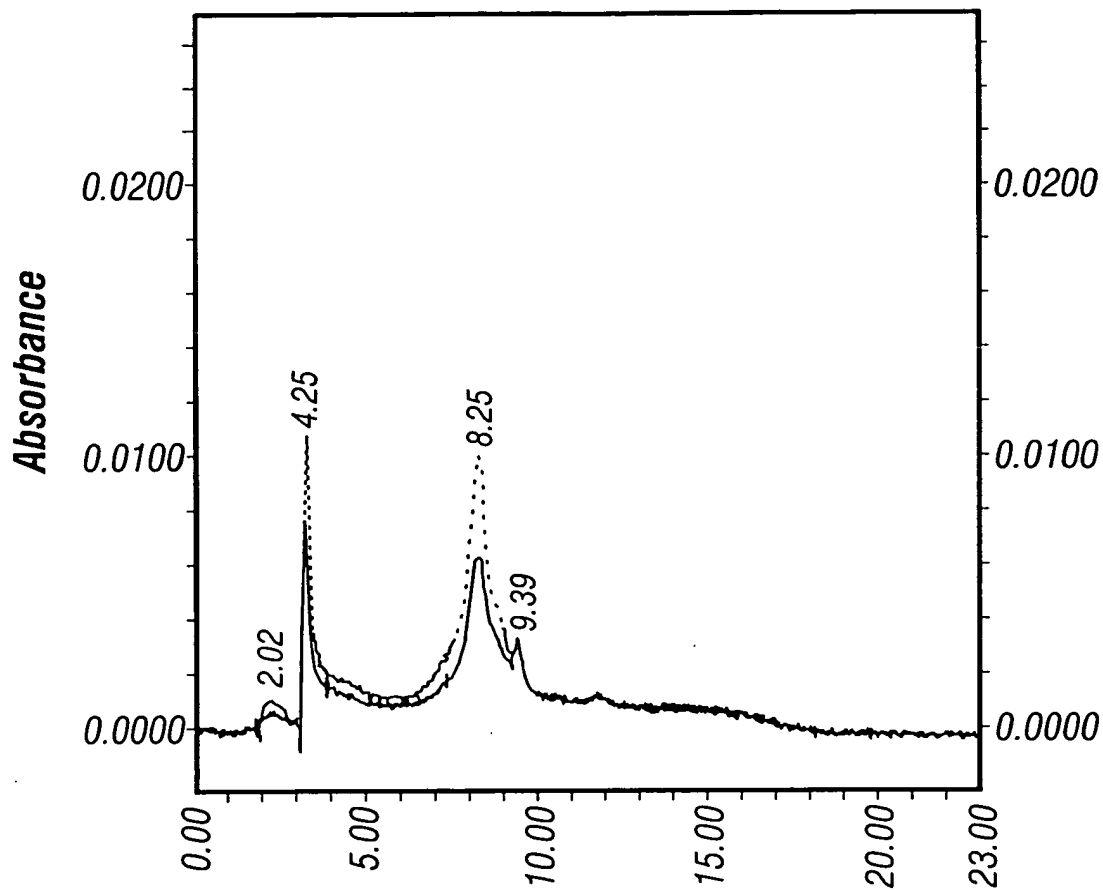


FIG. 8A

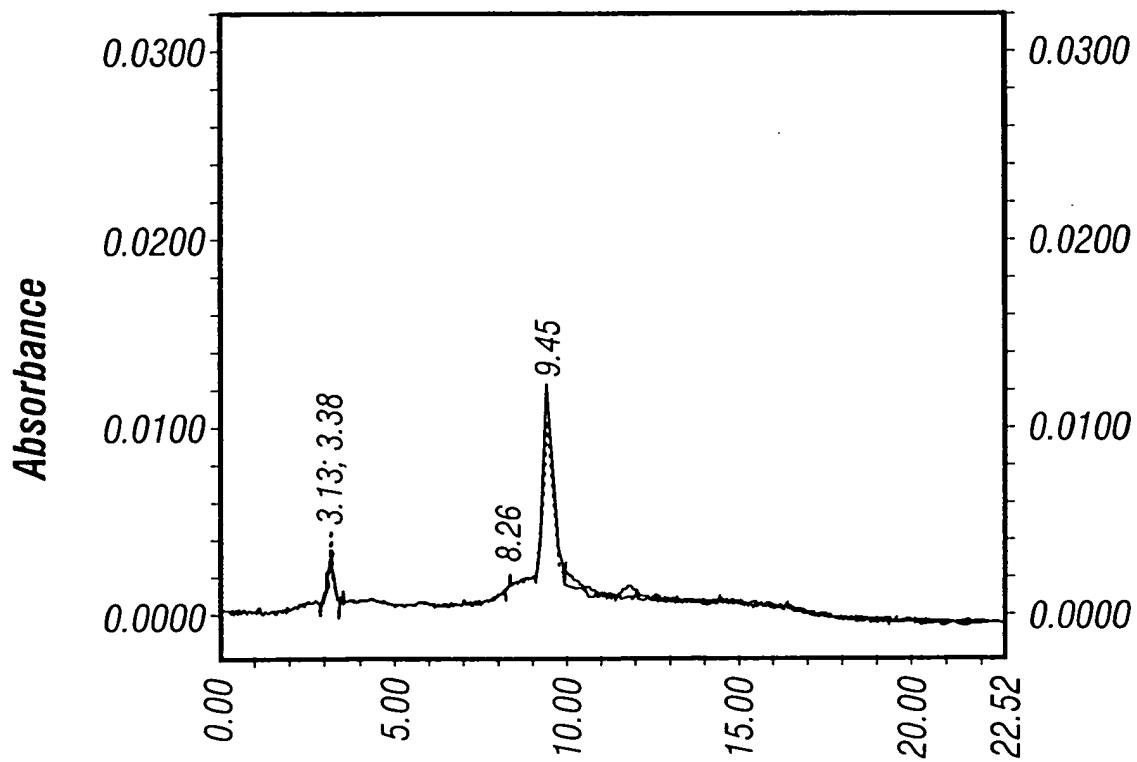
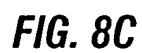


FIG. 8B



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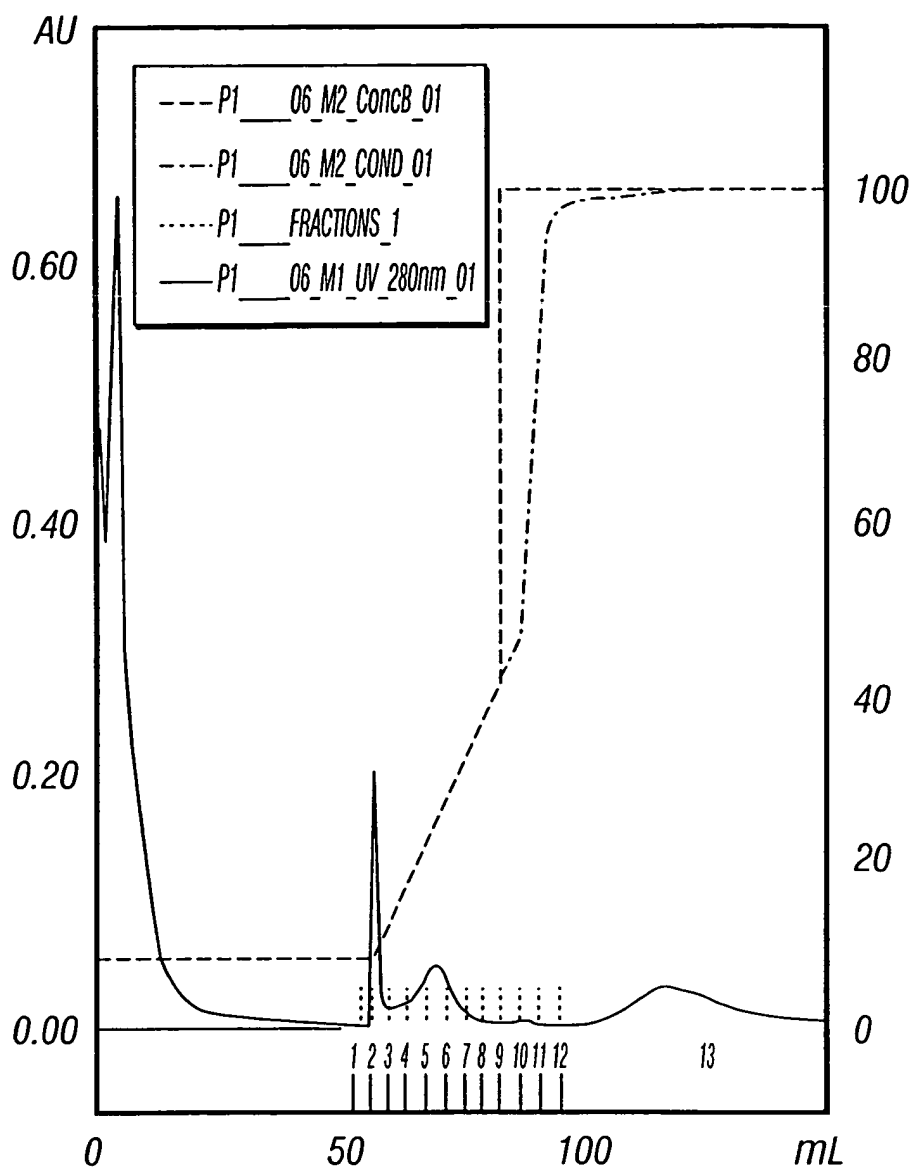


FIG. 9

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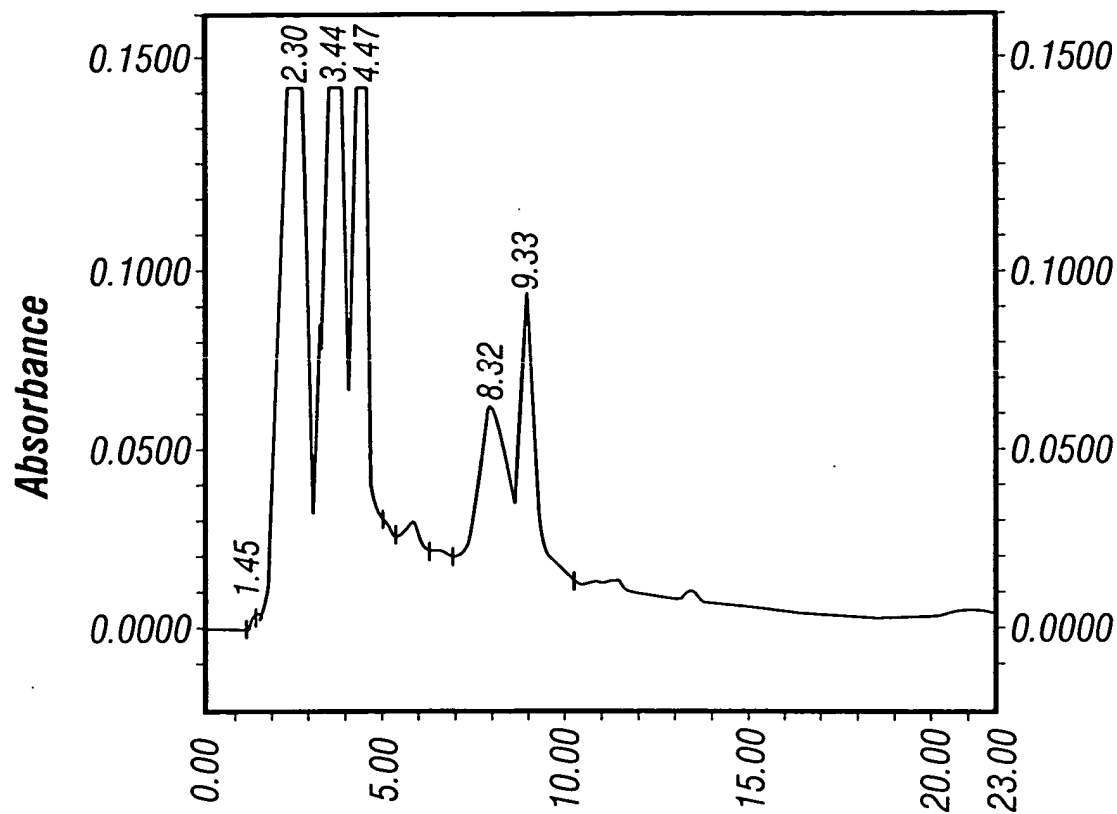


FIG. 10A

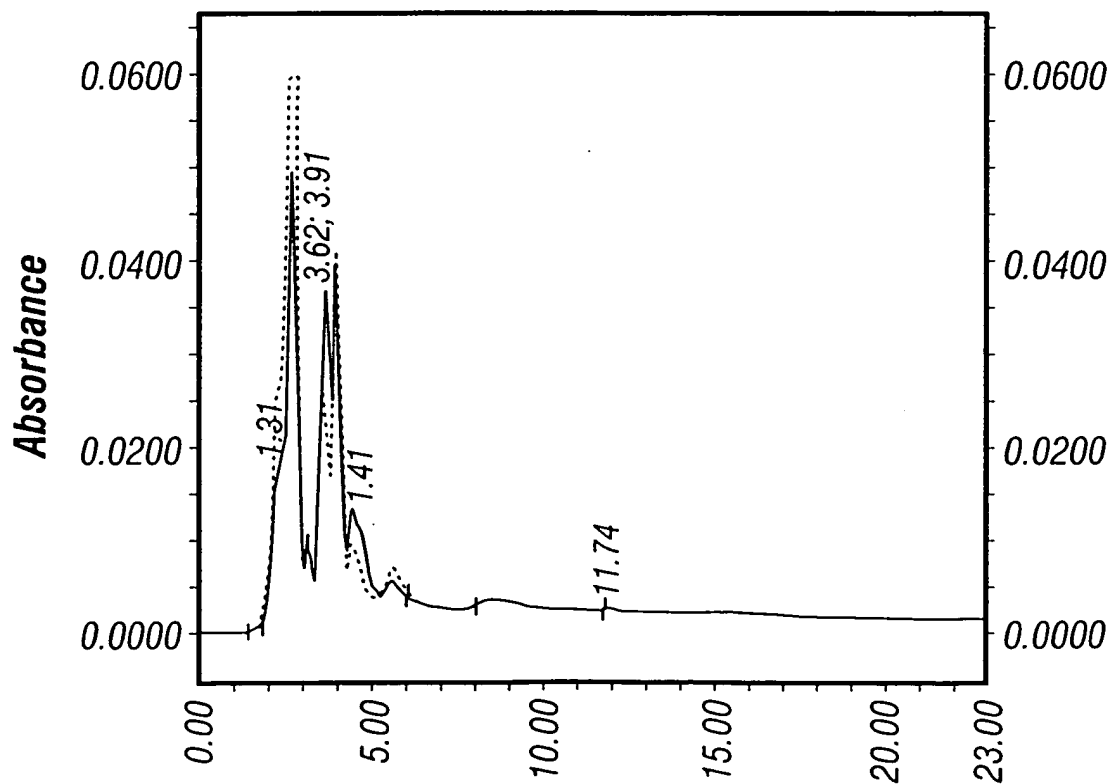


FIG. 10B

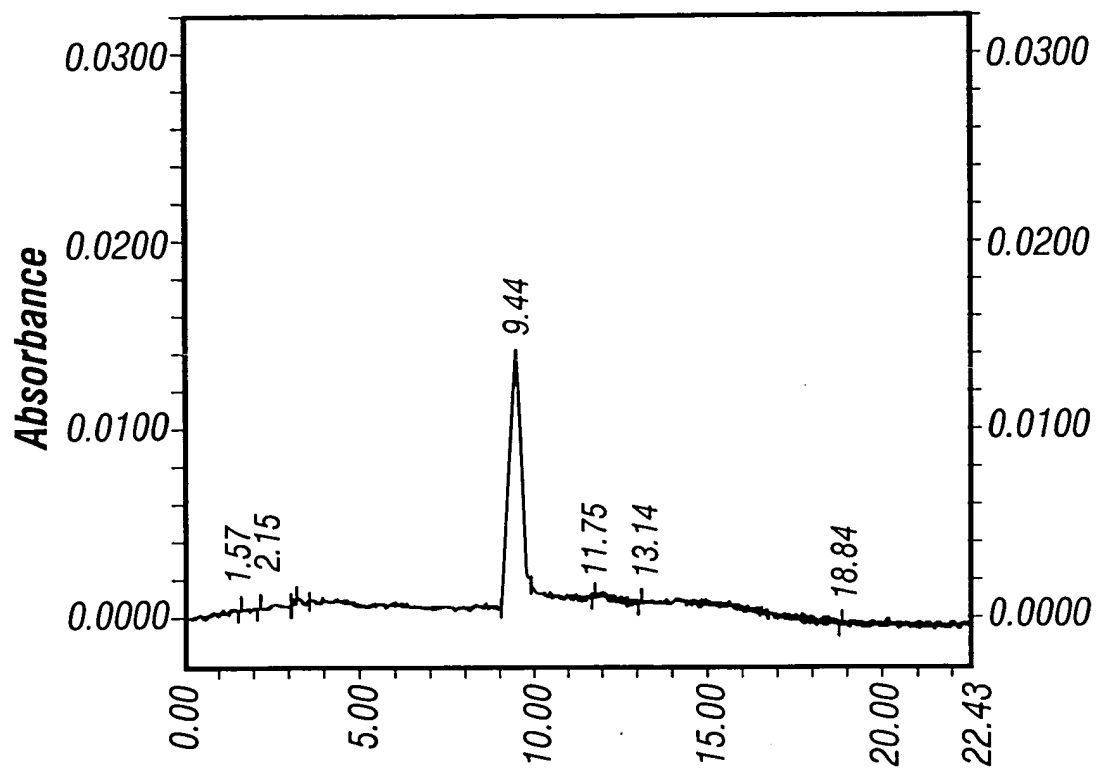


FIG. 10C

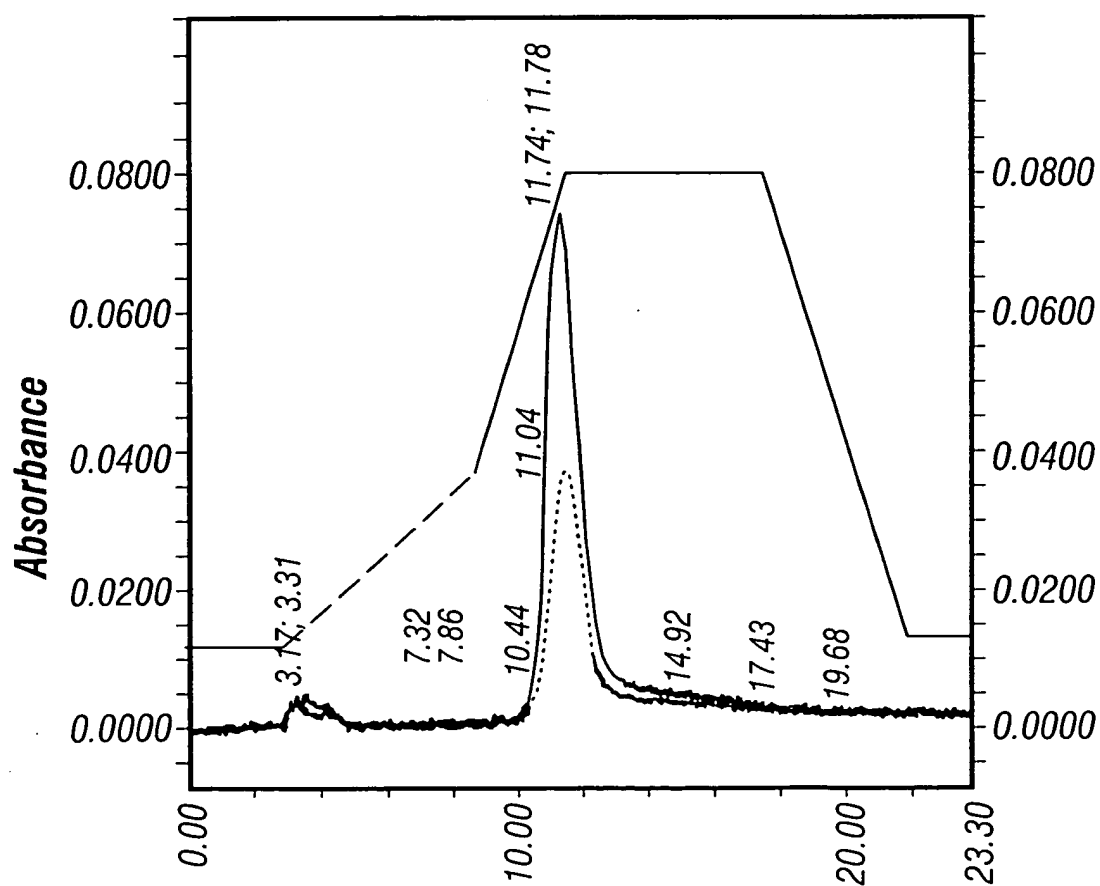


FIG. 10D

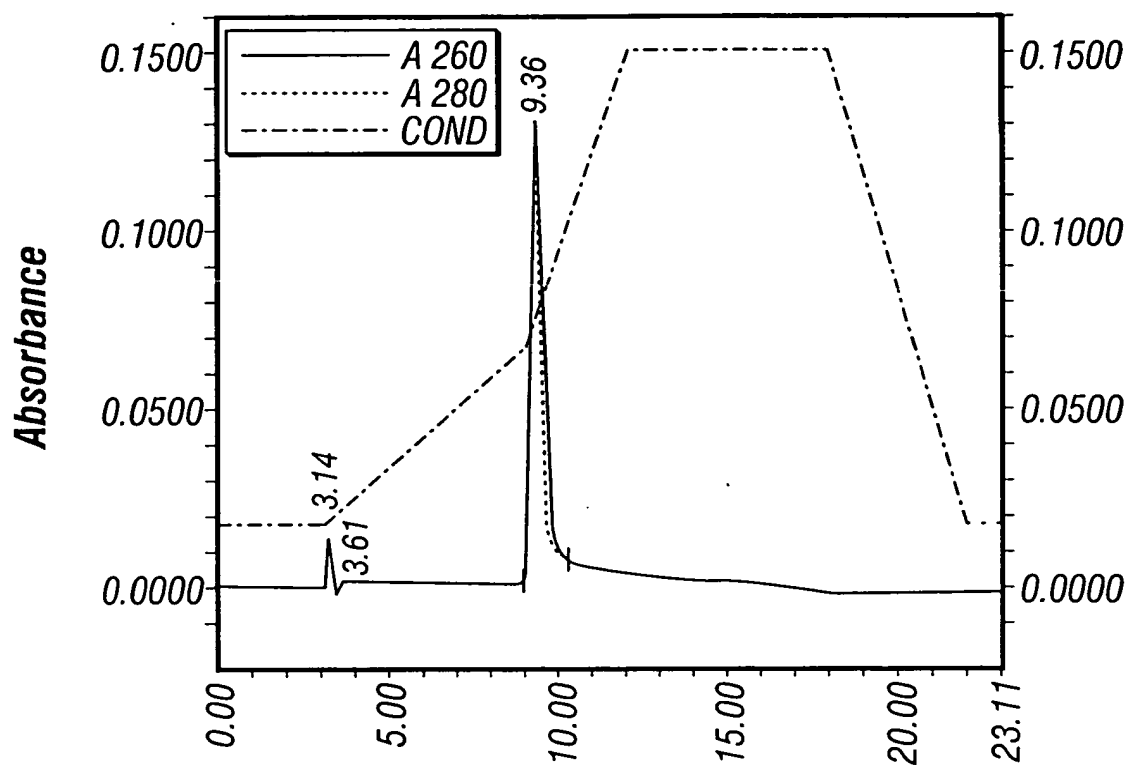


FIG. 10E

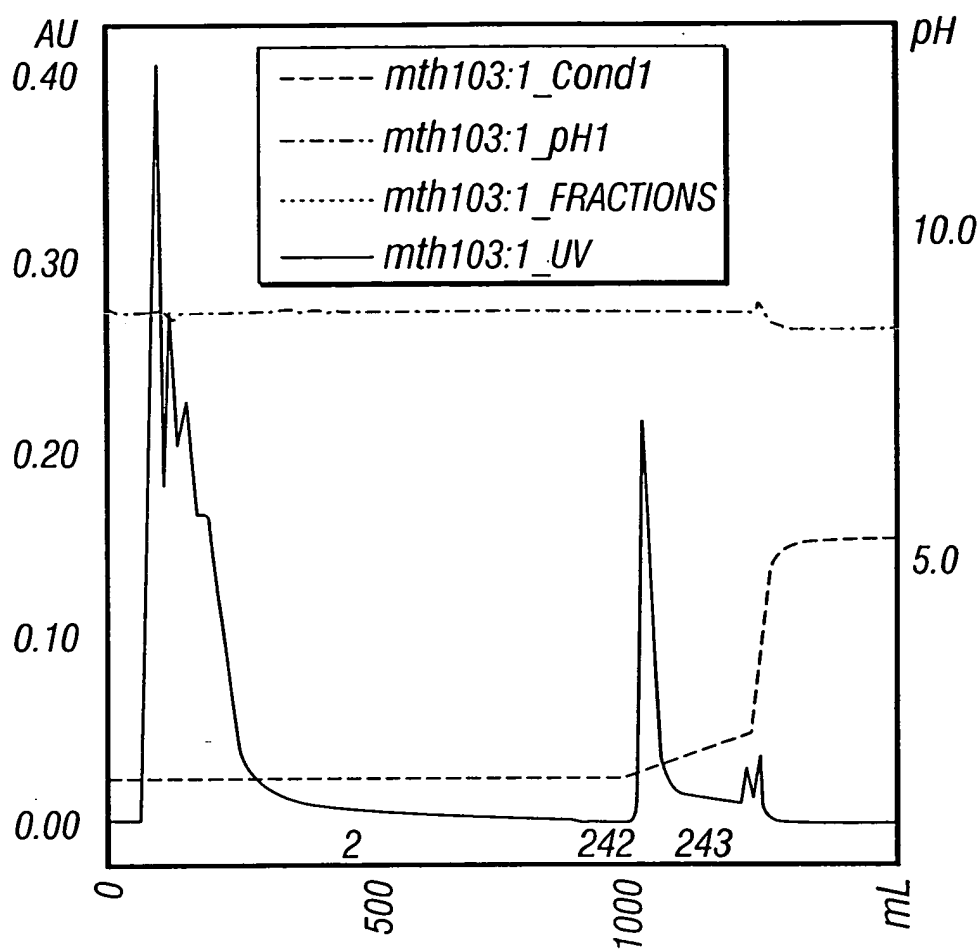


FIG. 11

FOOTNOTES: 60908860



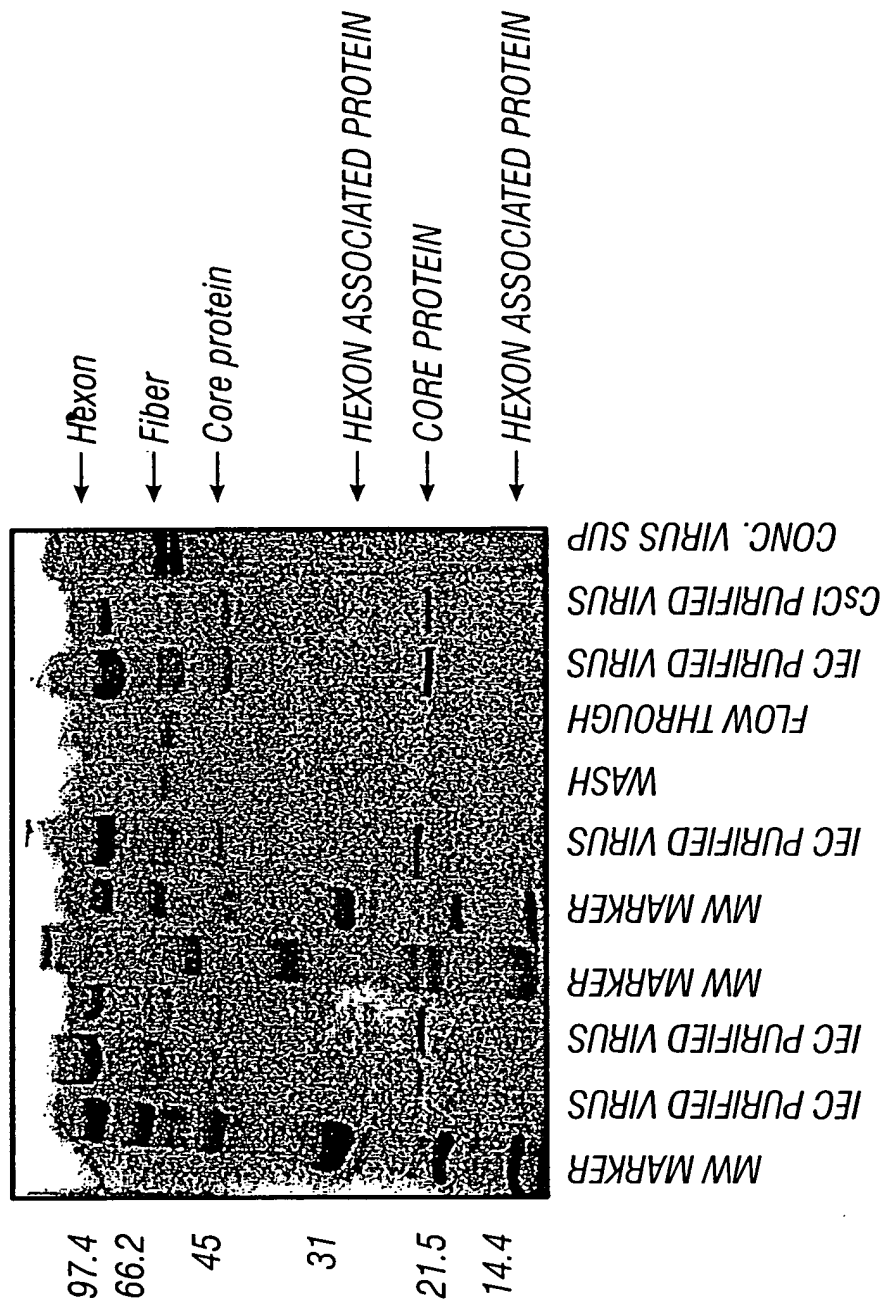


FIG. 12

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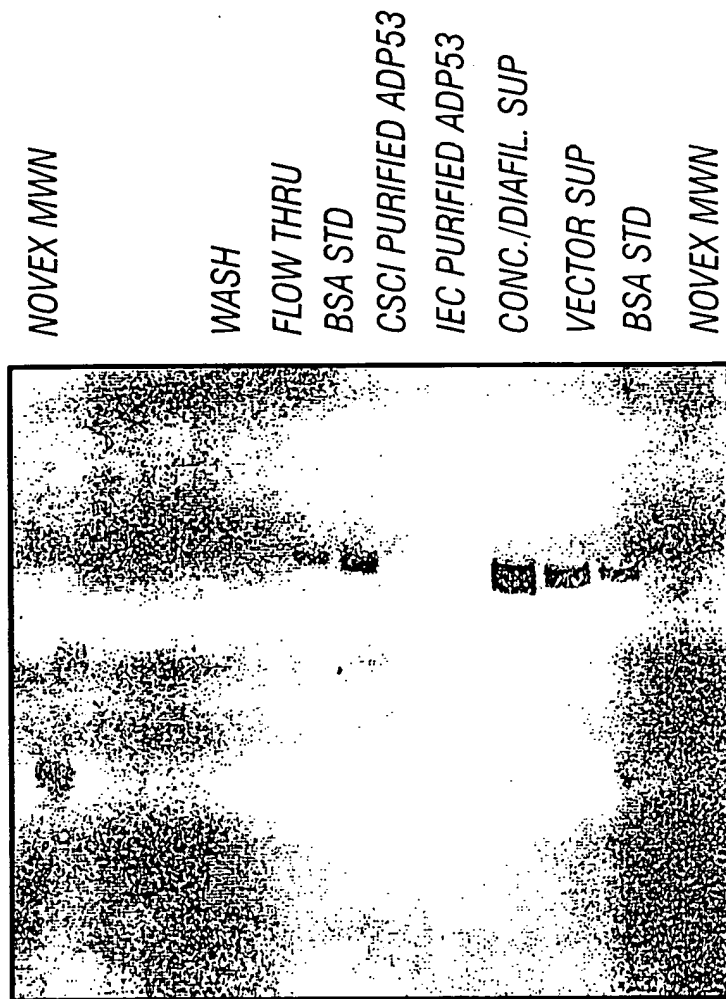


FIG. 13

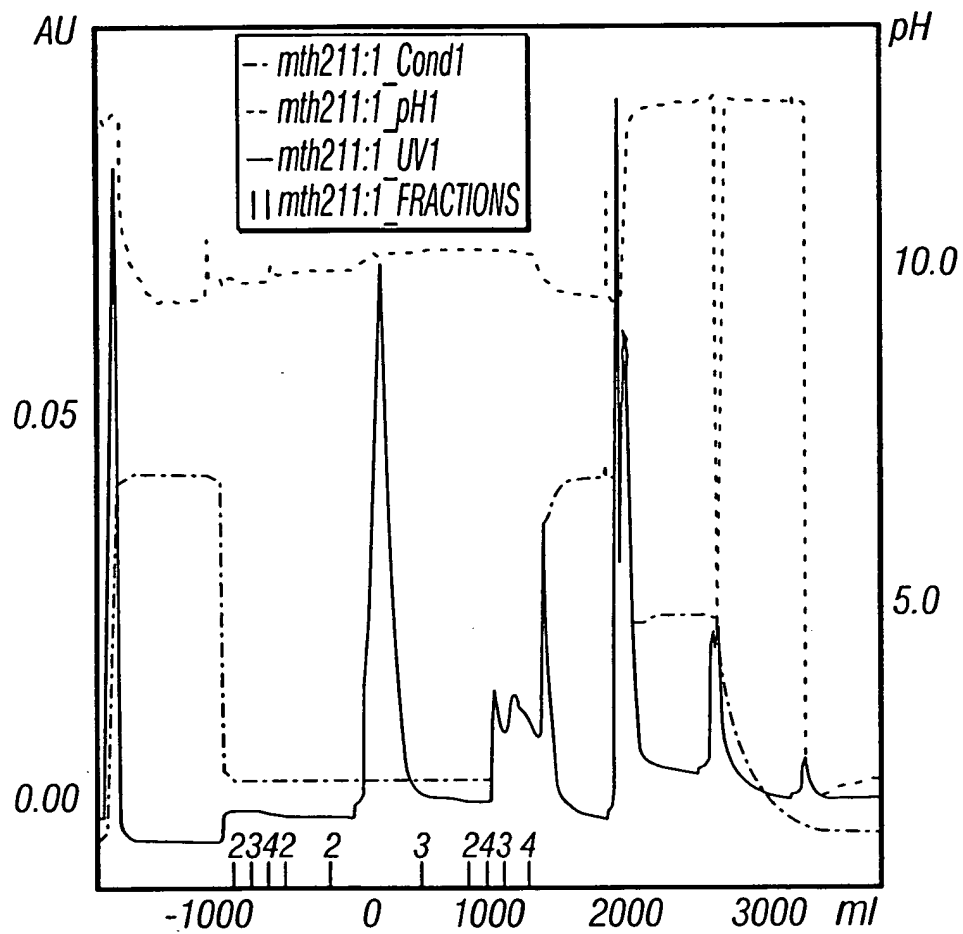


FIG. 14

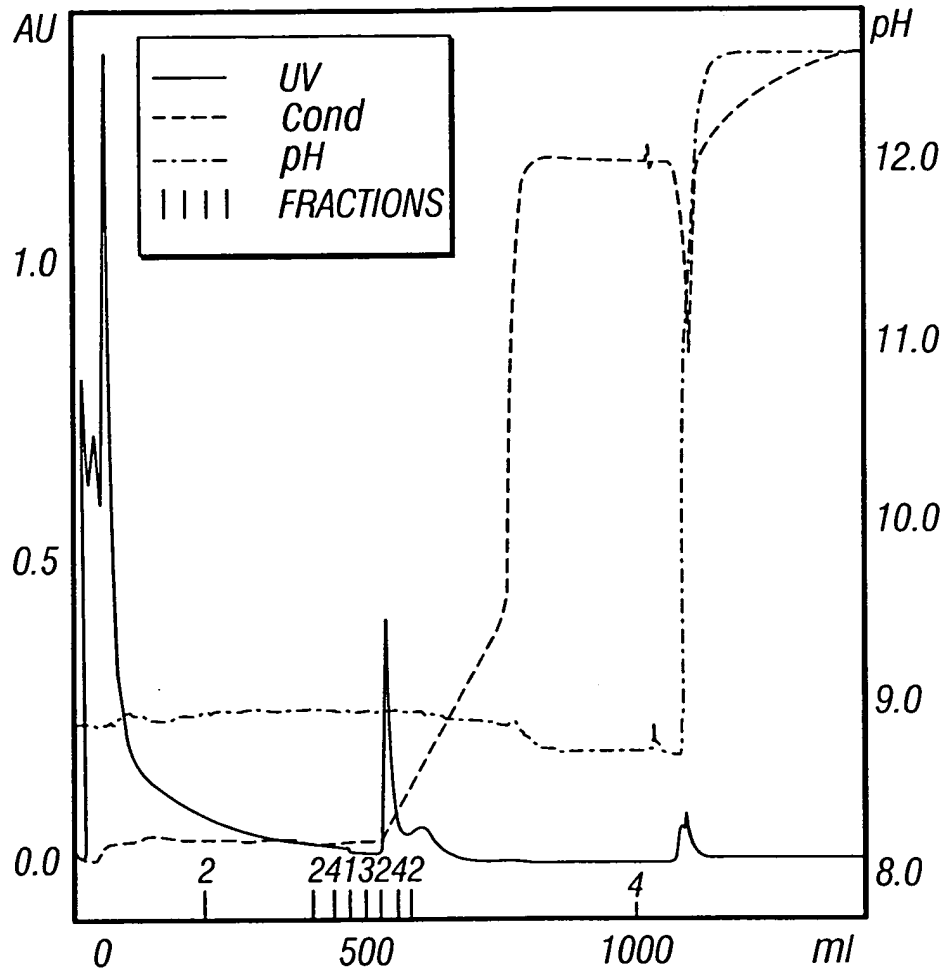


FIG. 15

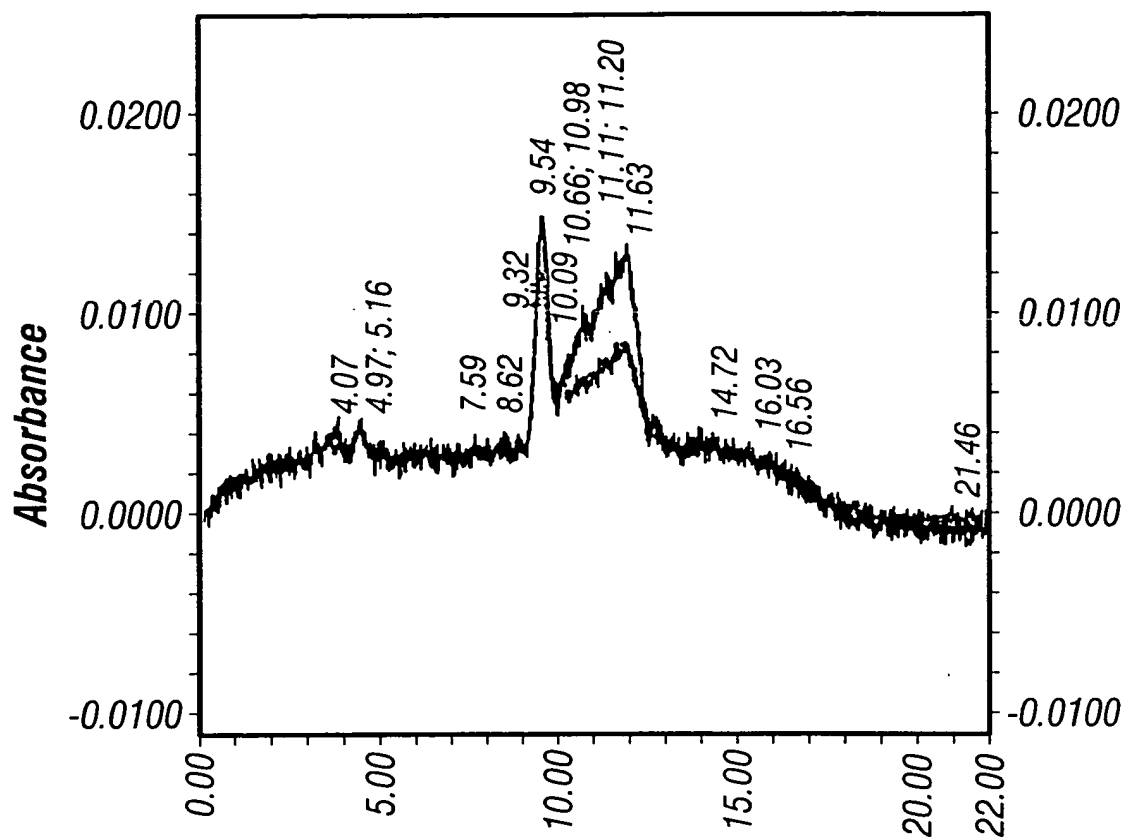


FIG. 16A

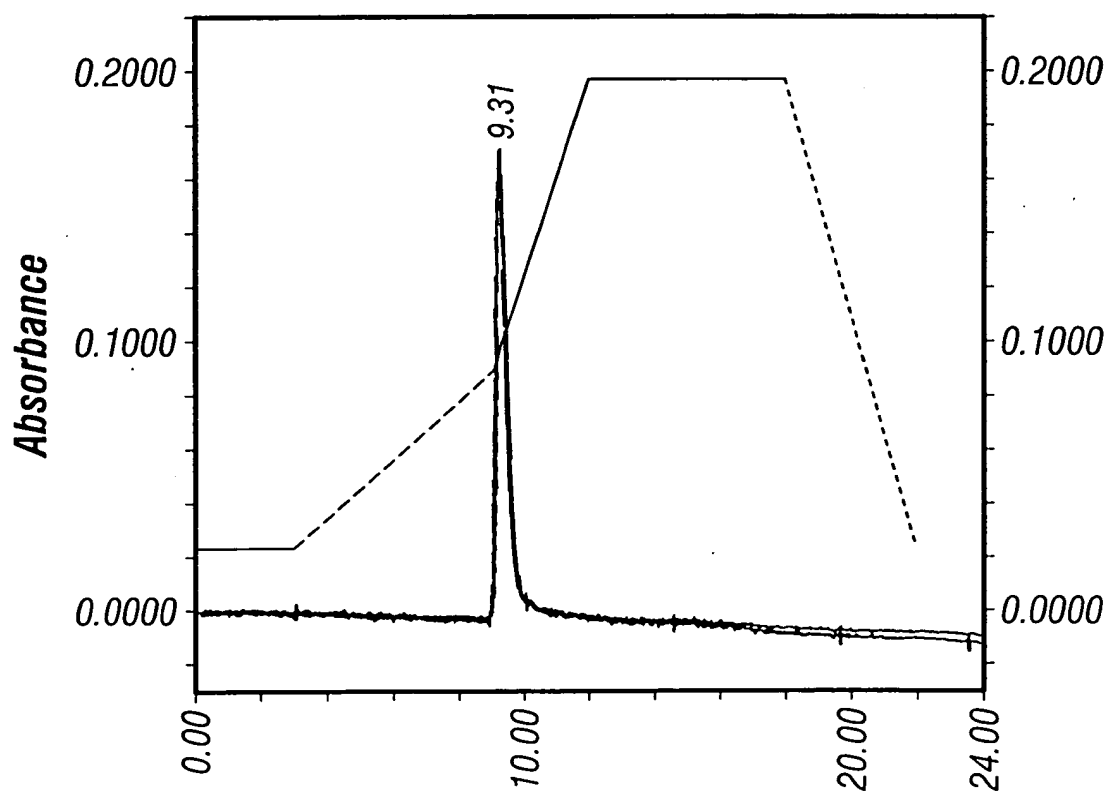


FIG. 16B

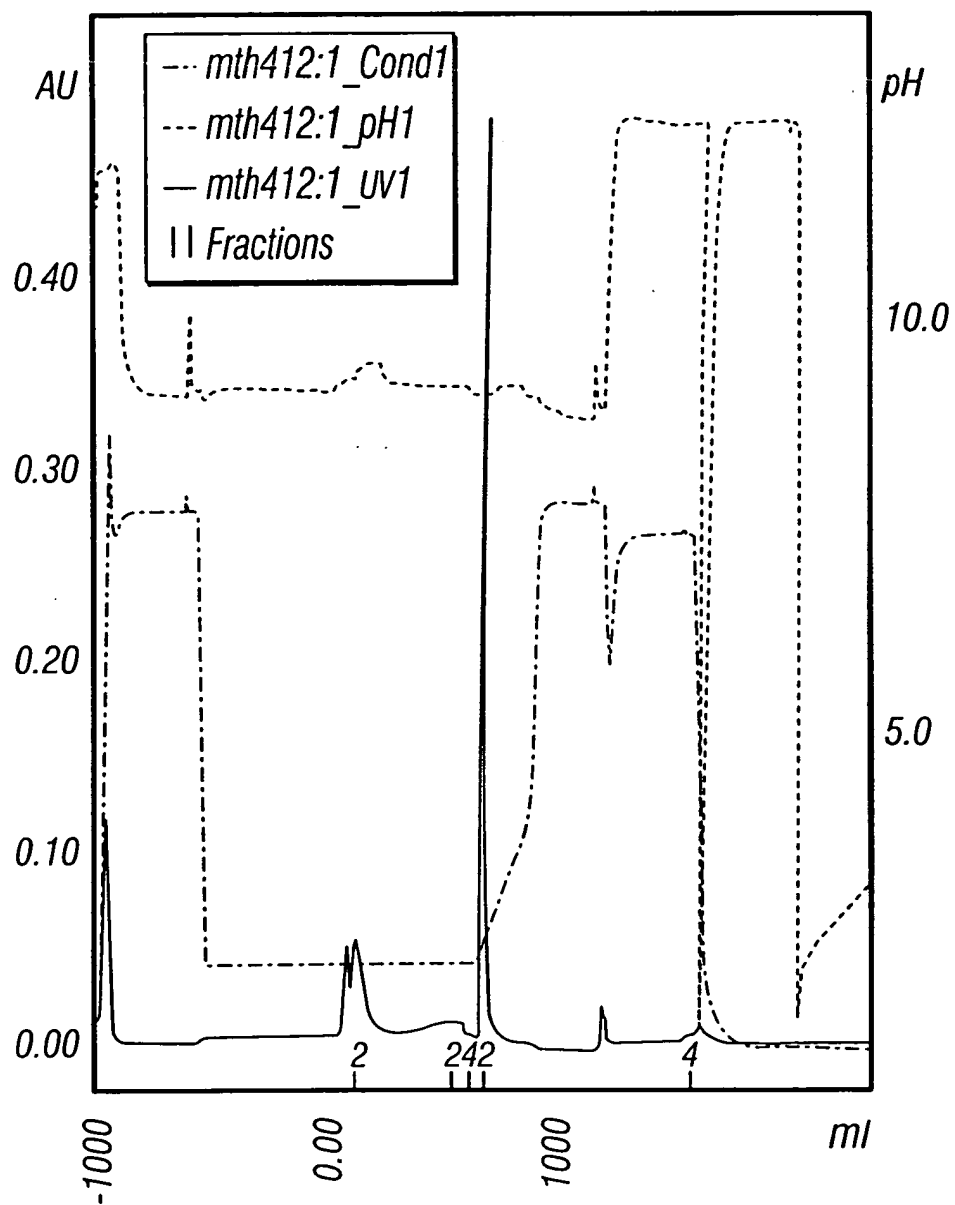


FIG. 17

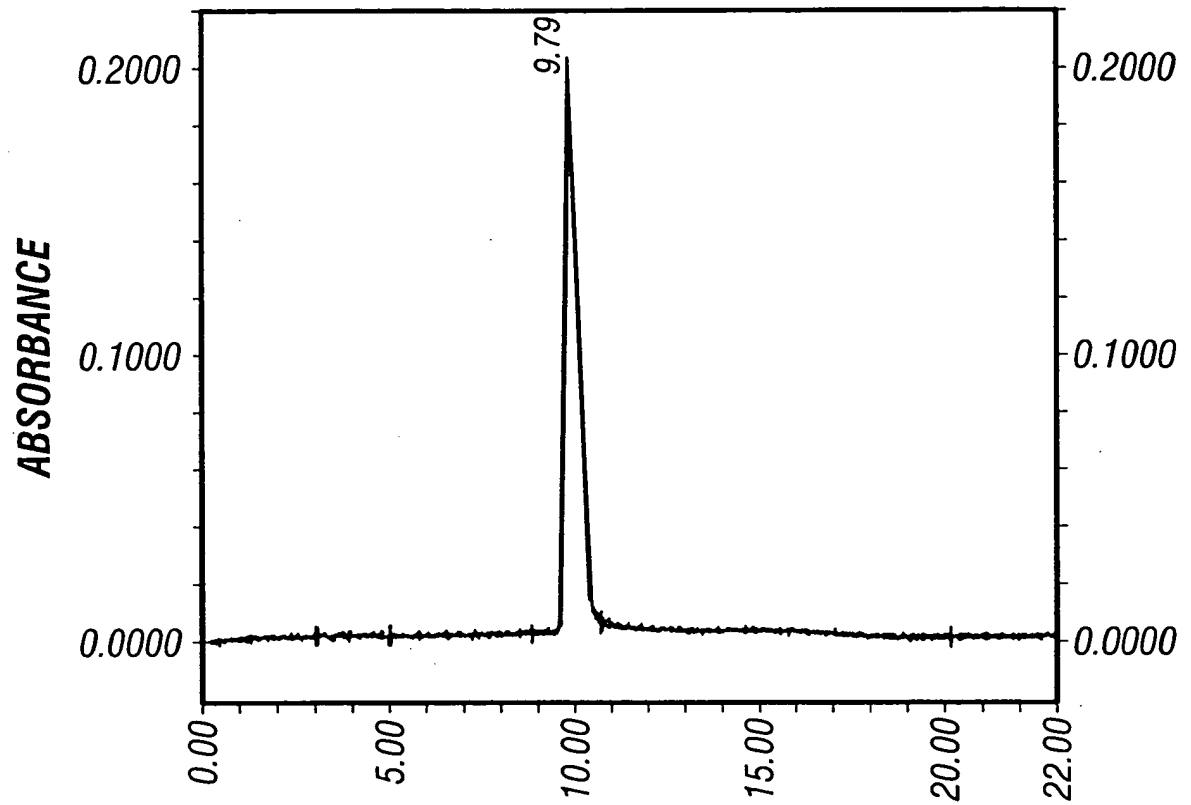


FIG. 18

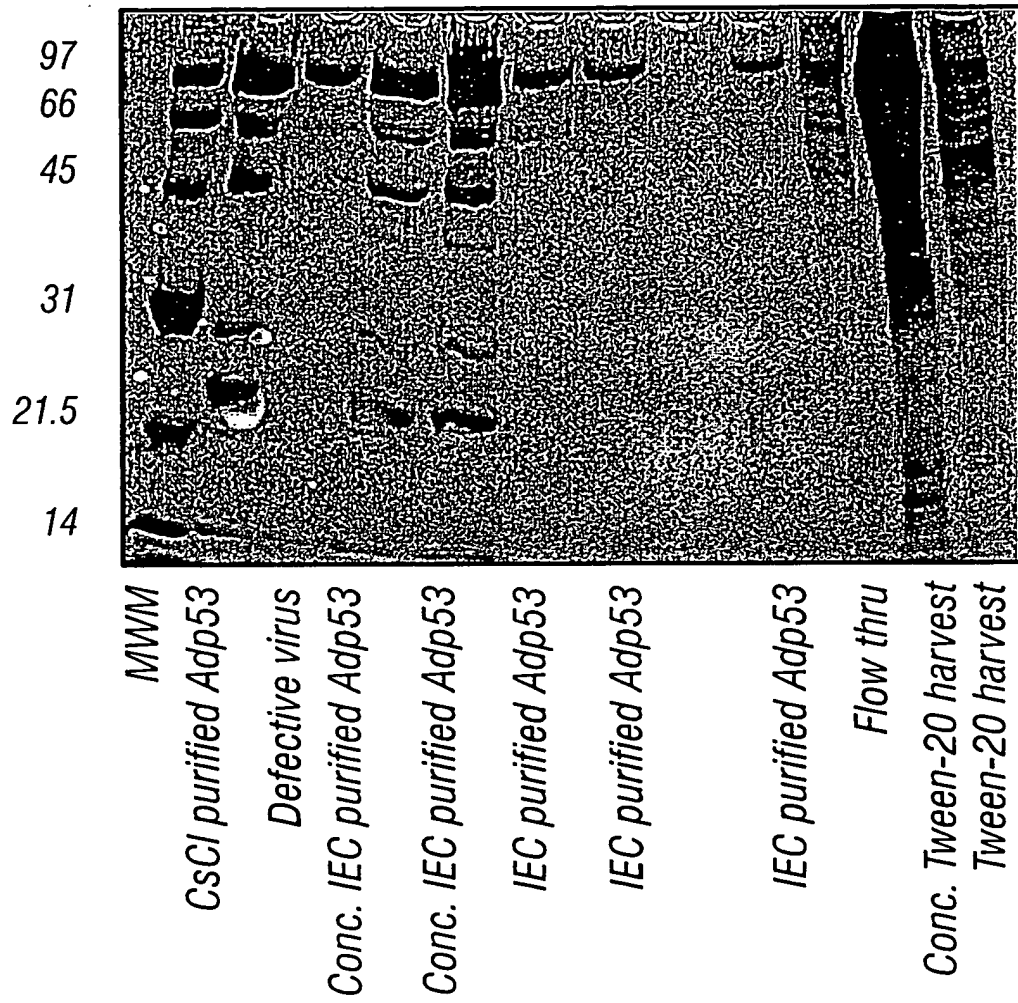


FIG. 19A



FOOTED 60908860

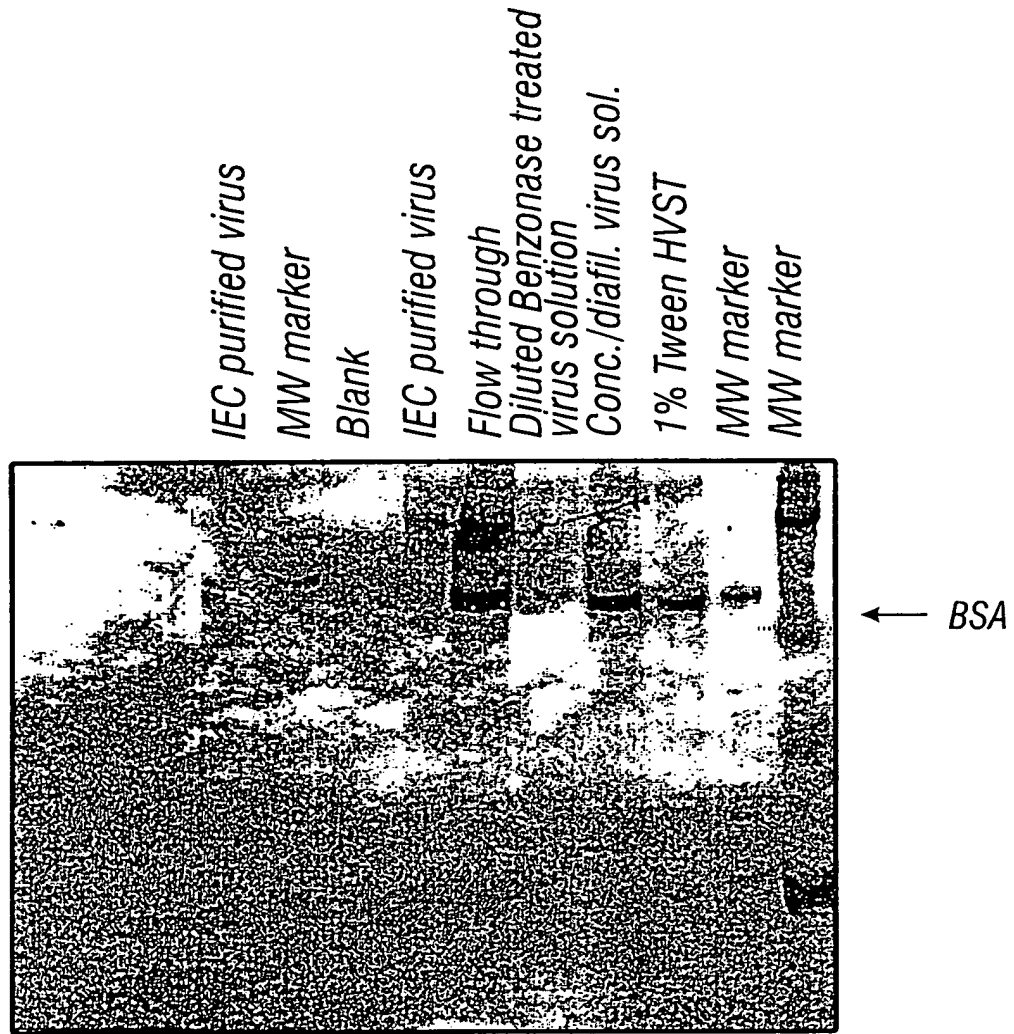


FIG. 19B

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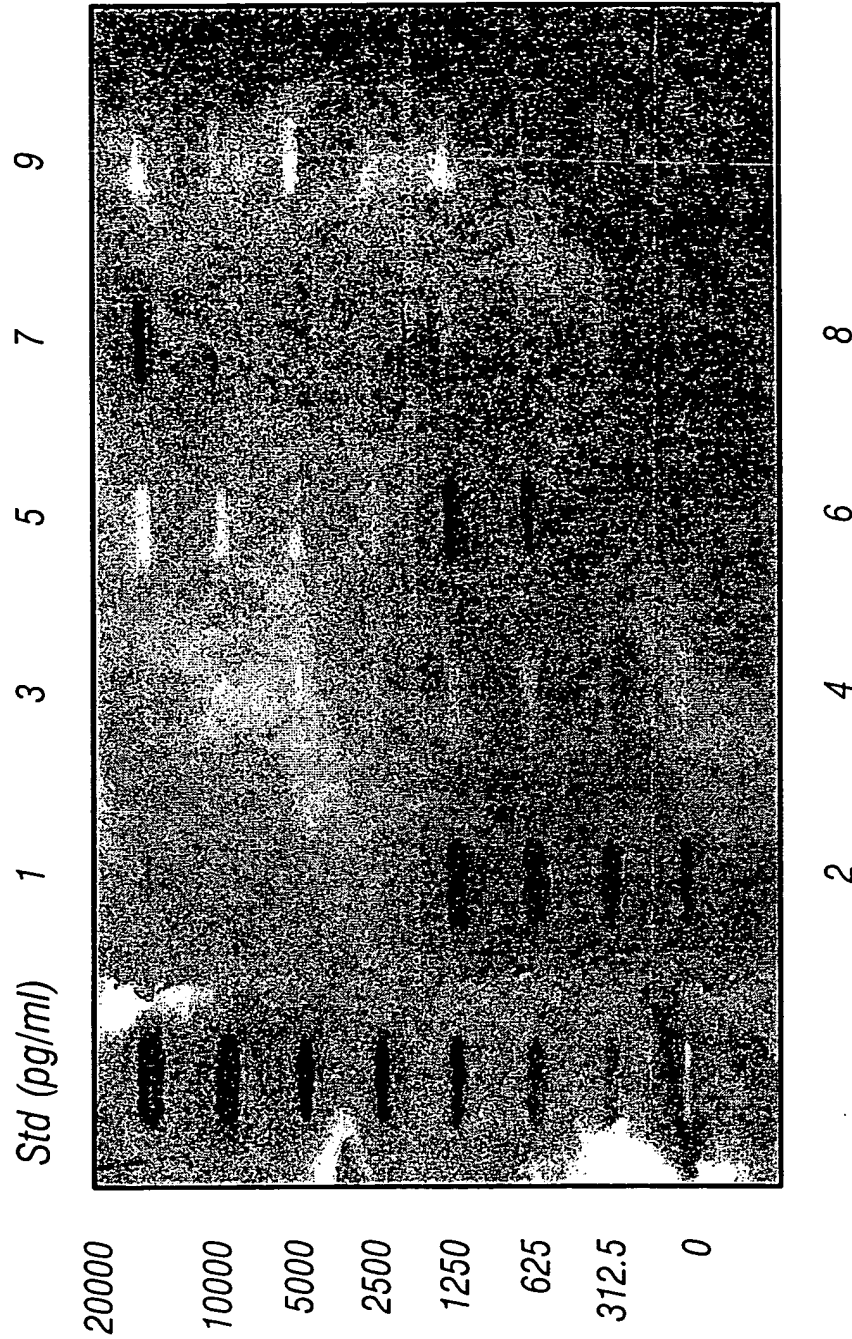


FIG. 19C

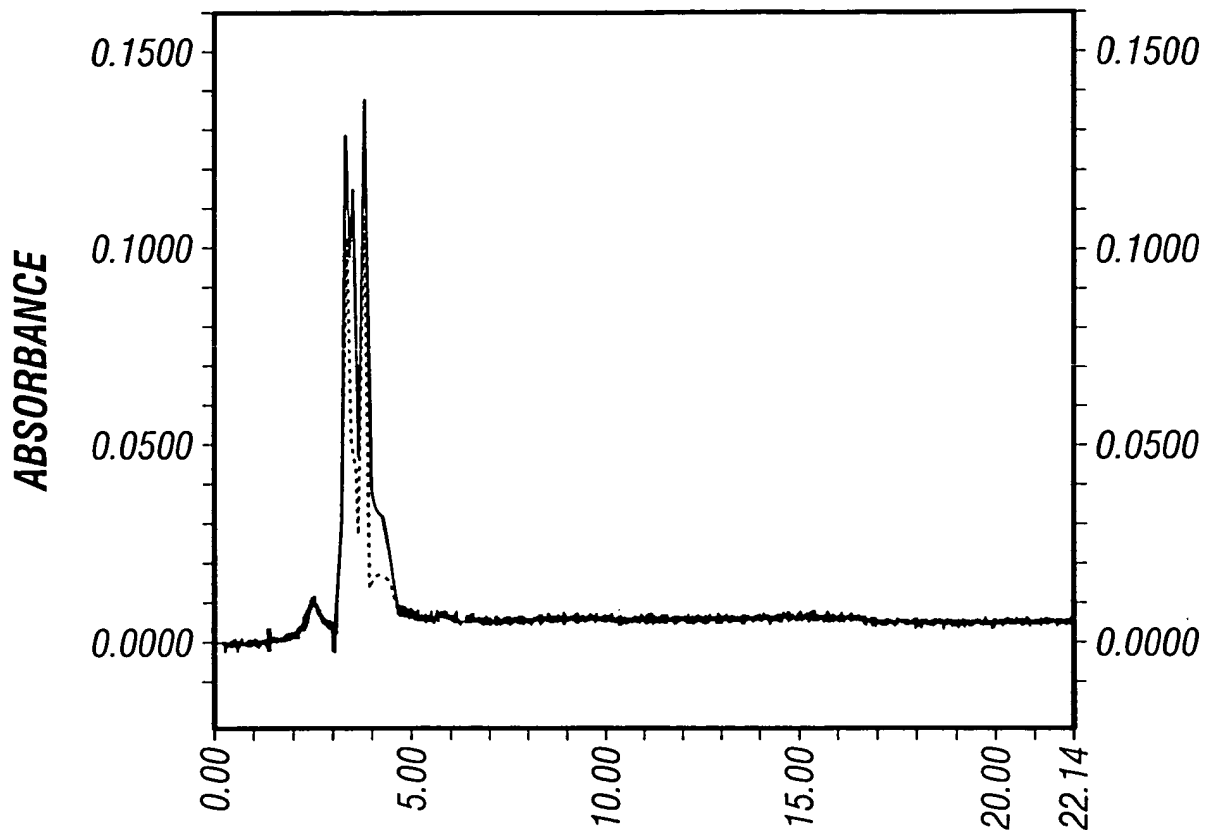


FIG. 20A

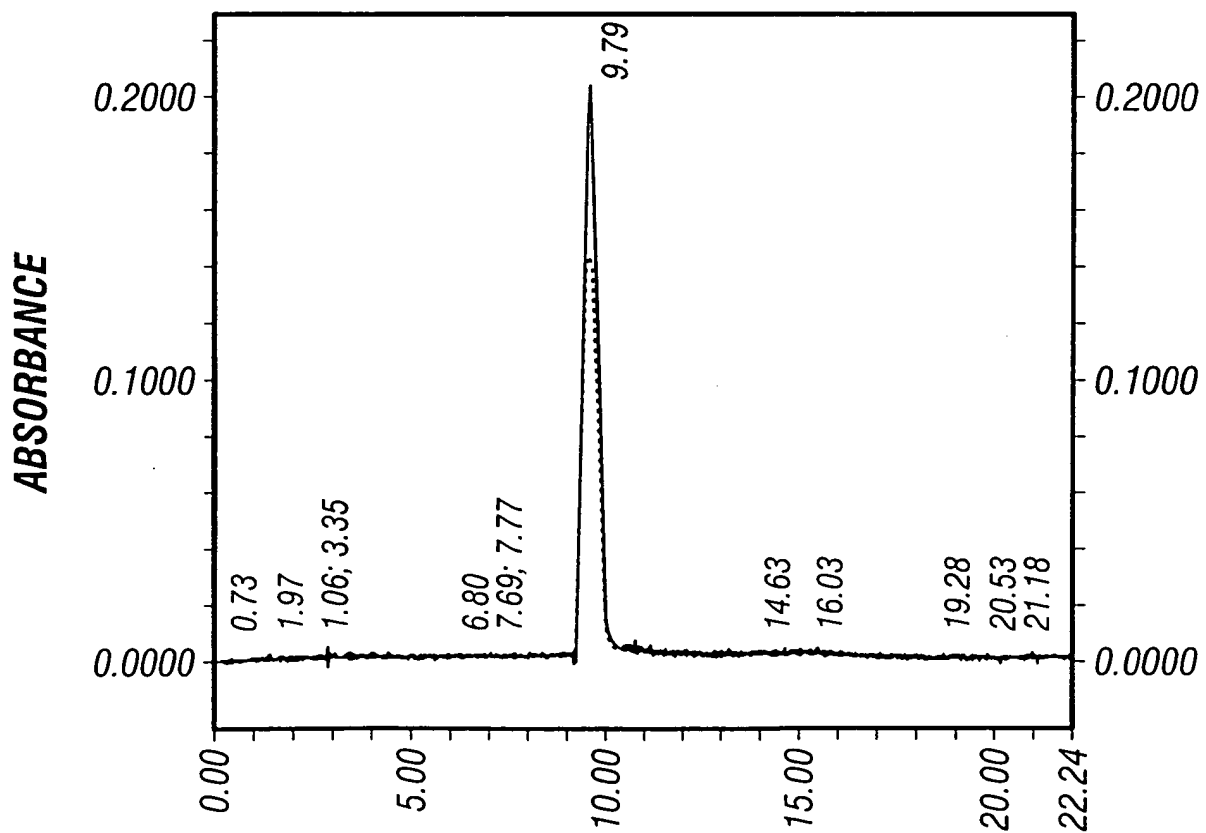
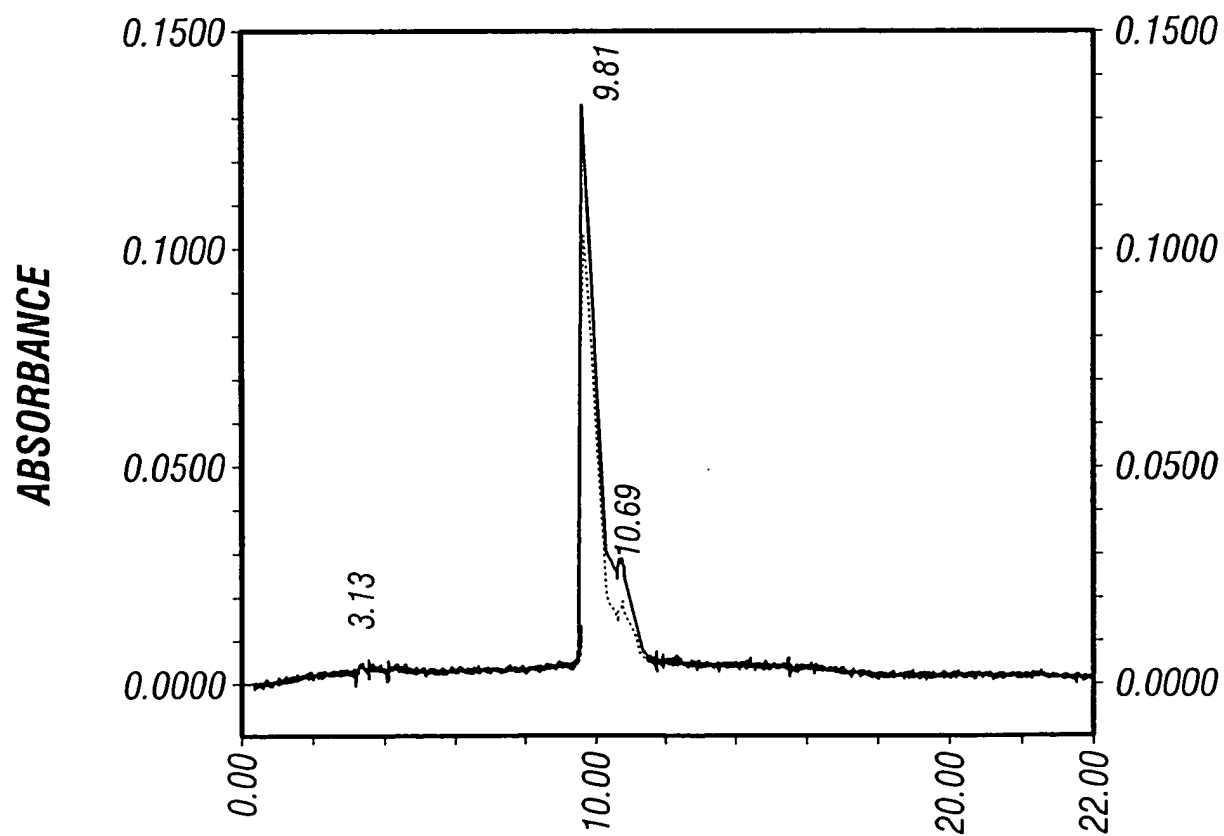
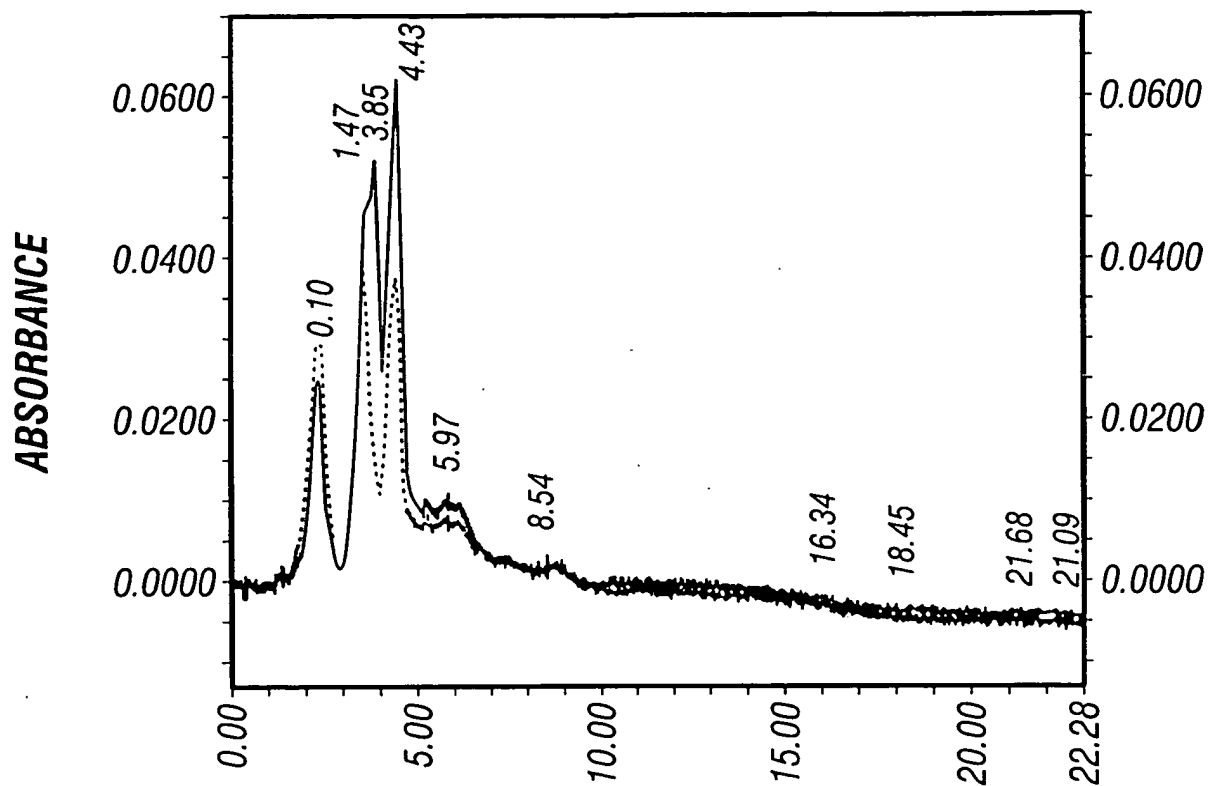


FIG. 20B



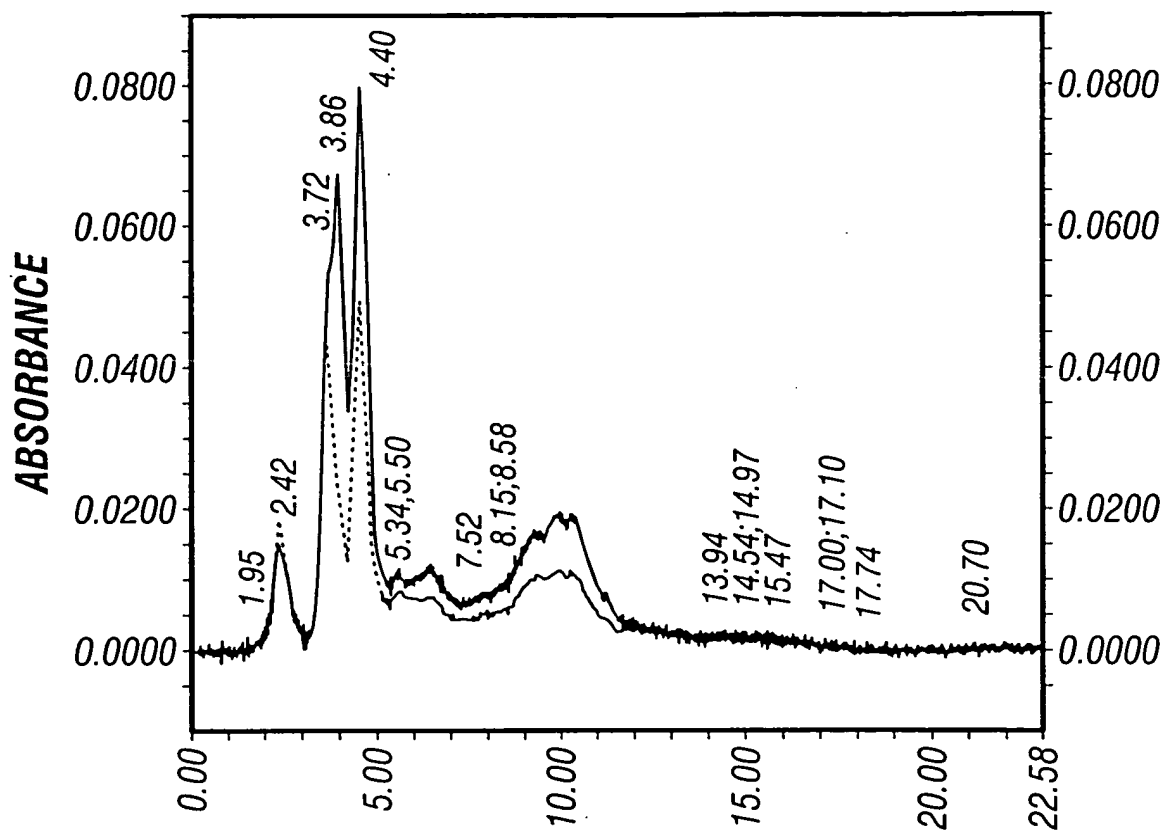


FIG. 20E

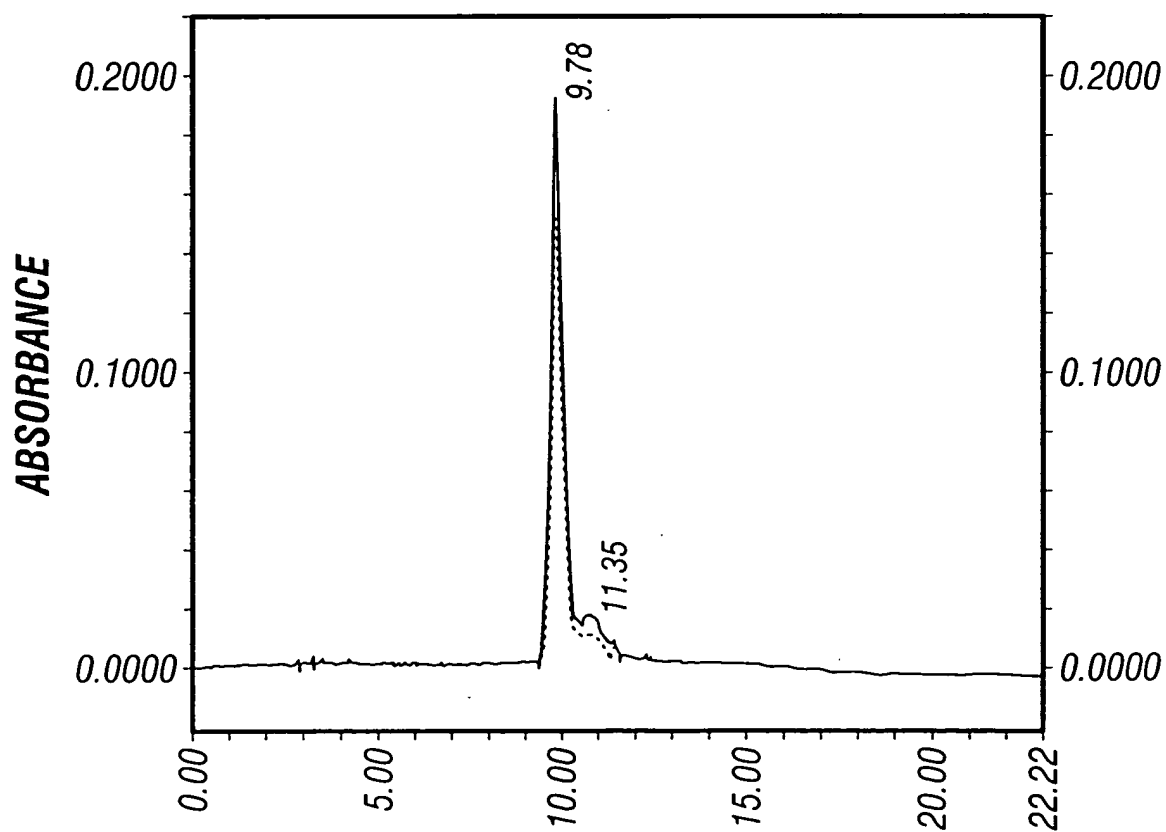
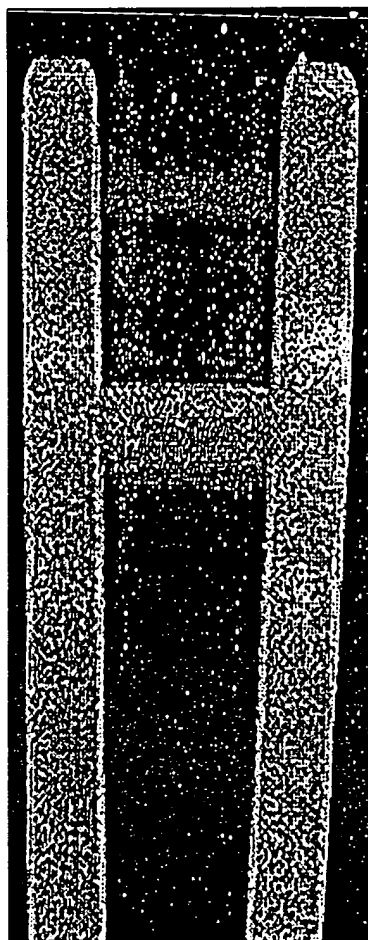


FIG. 20F



← Defective virus band  
(titer:  $3 \times 10^7$  PFU/ml)

← Intact virus band  
(titer:  $1 \times 10^{11}$  PFU/ml)

FIG. 21

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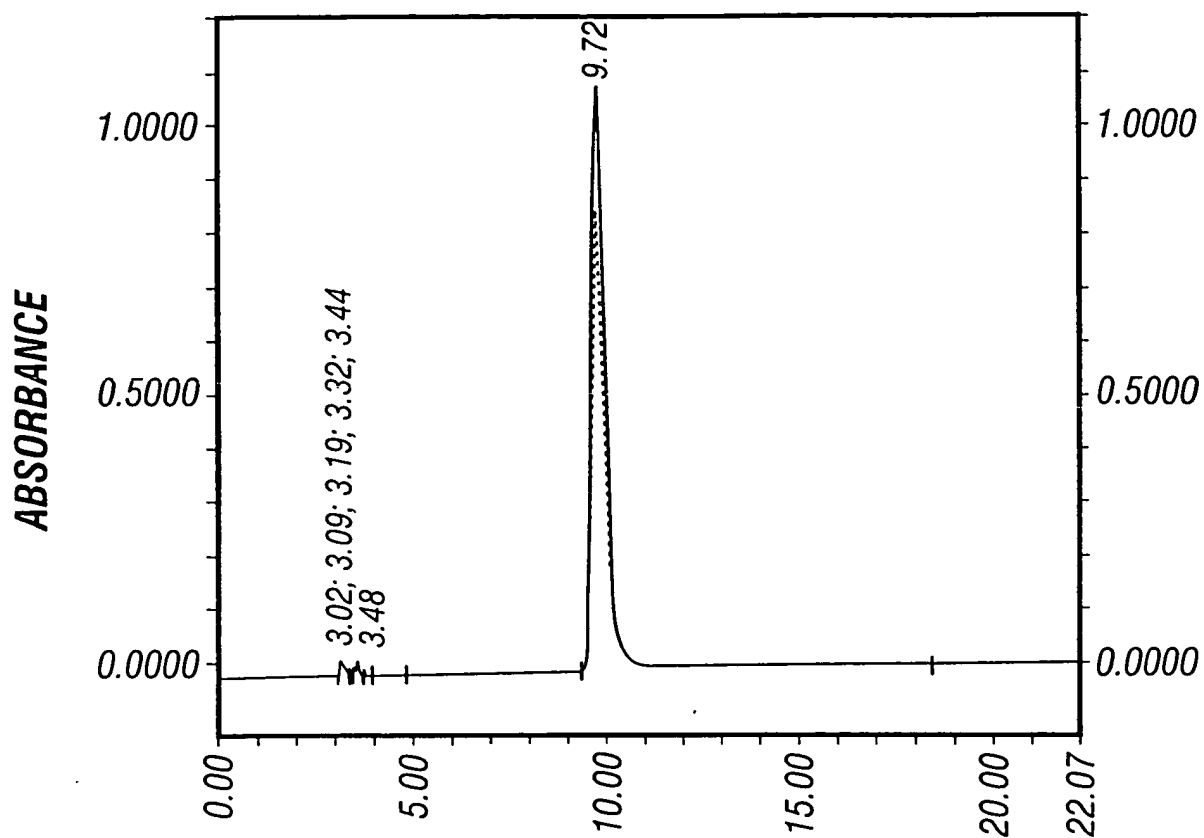


FIG. 22A

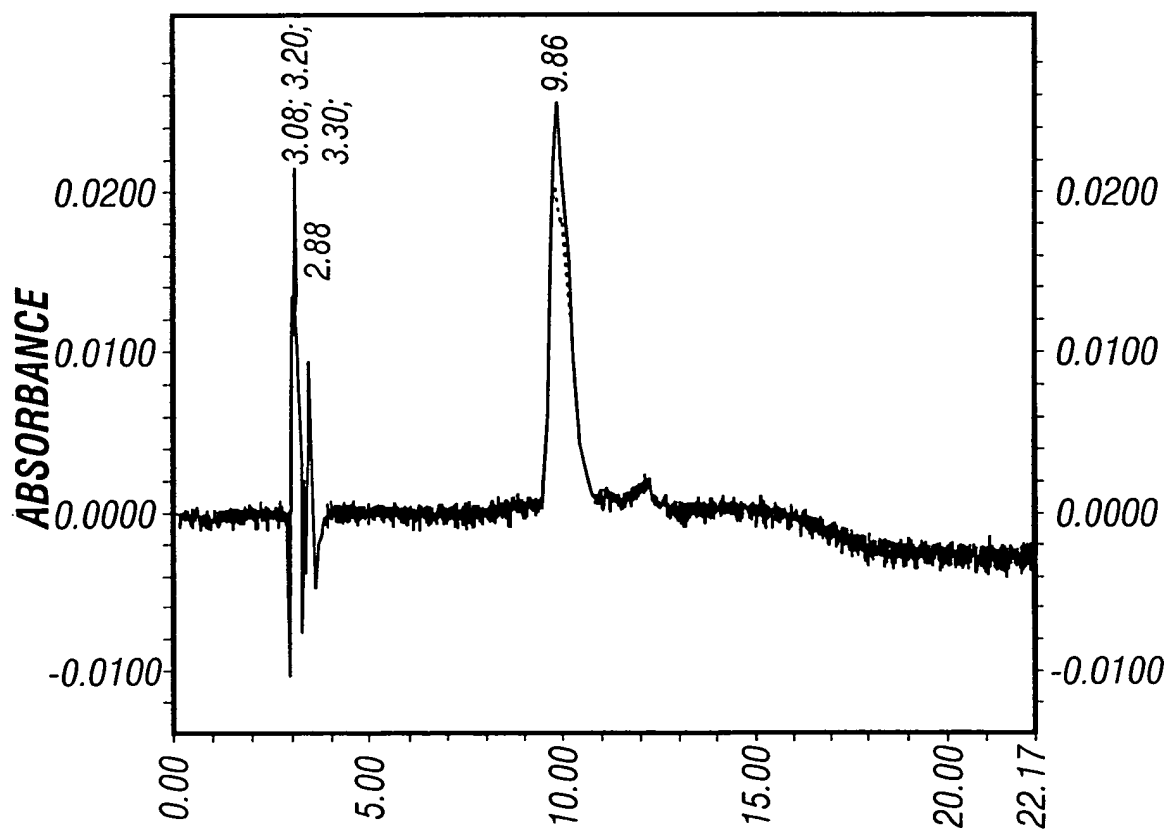


FIG. 22B

		Titer (PFU/ml)	Vol. (ml)	Yield (PFU)	Recovery %	
					Step	Acc.
Cube	(low perfusion rate, keep glucose > 1g/L)					
	↓ 1% Tween-20 in buffer A					
Harvest						
	↓ Clarification and Filtration (0.22 $\mu$ m)					
Virus solution		$2.6 \times 10^9$	1900	$4.9 \times 10^{12}$		
	↓ Conc./diaf. (10-fold conc., diaf. into 1m NaCl buffer A)					
Conc. sup		$2.5 \times 10^{10}$	200	$5 \times 10^{12}$	102%	
	↓ Benzonase treatment (O/N, RT, 100u/ml)					
Treated sup						
	↓ Diluted with water to conductivity = 22-25 mS/cm					
Diluted virus solution		$7 \times 10^9$	700	$4.9 \times 10^{12}$	98%	100%
	↓					
purified virus		$1.5 \times 10^{10}$	240	$3.6 \times 10^{12}$	73%	73%
	↓ conc./diaf (5-fold conc.)					
Final purified product		$7 \times 10^{10}$	50	$3.5 \times 10^{12}$	97%	71%

FIG. 23



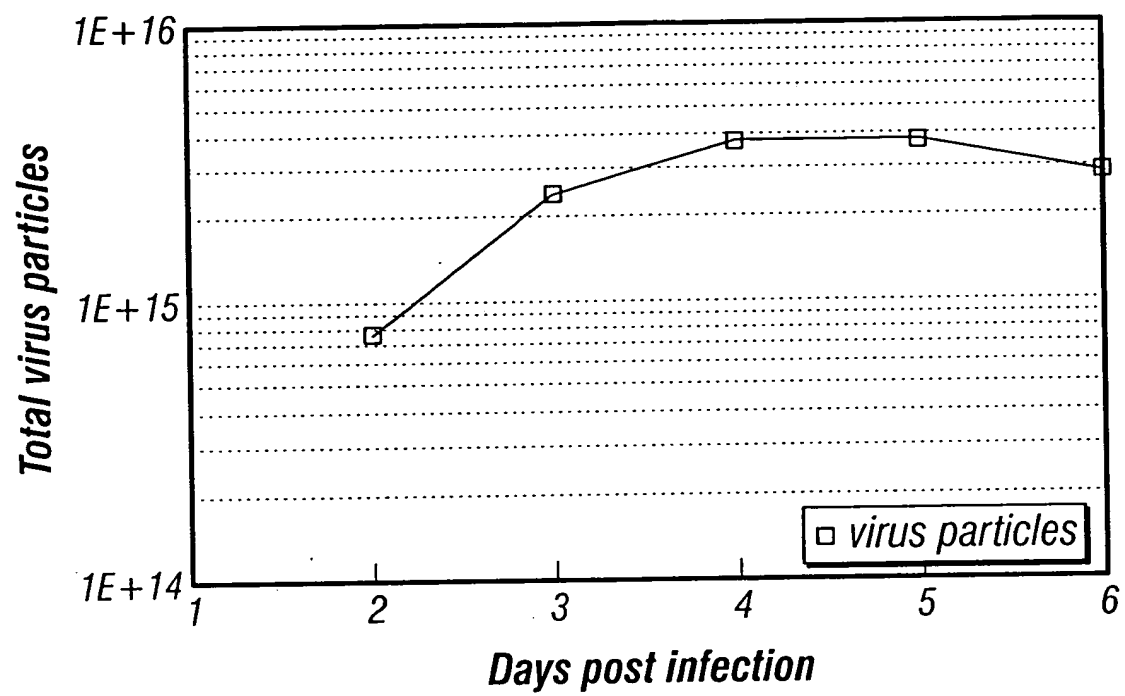


FIG. 24

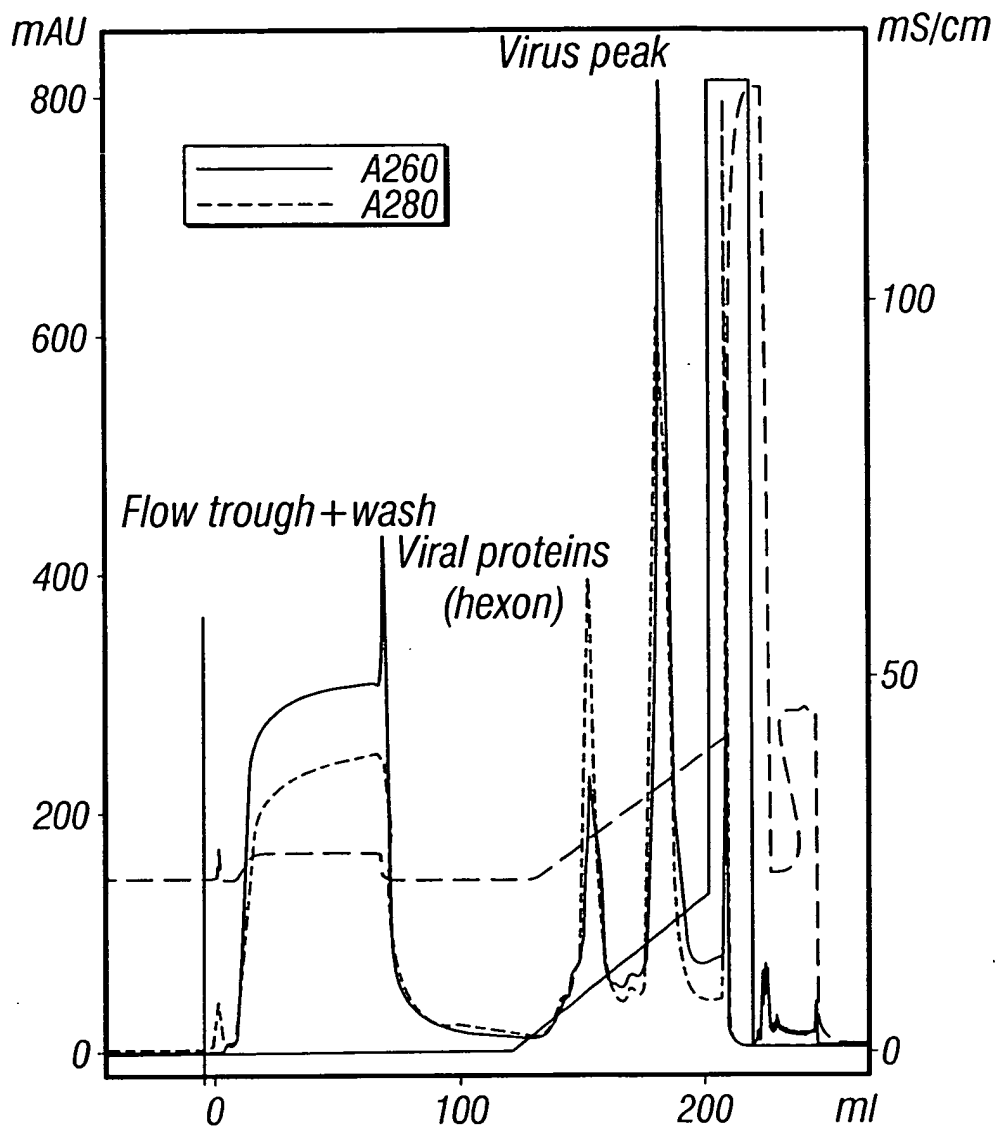


FIG. 25

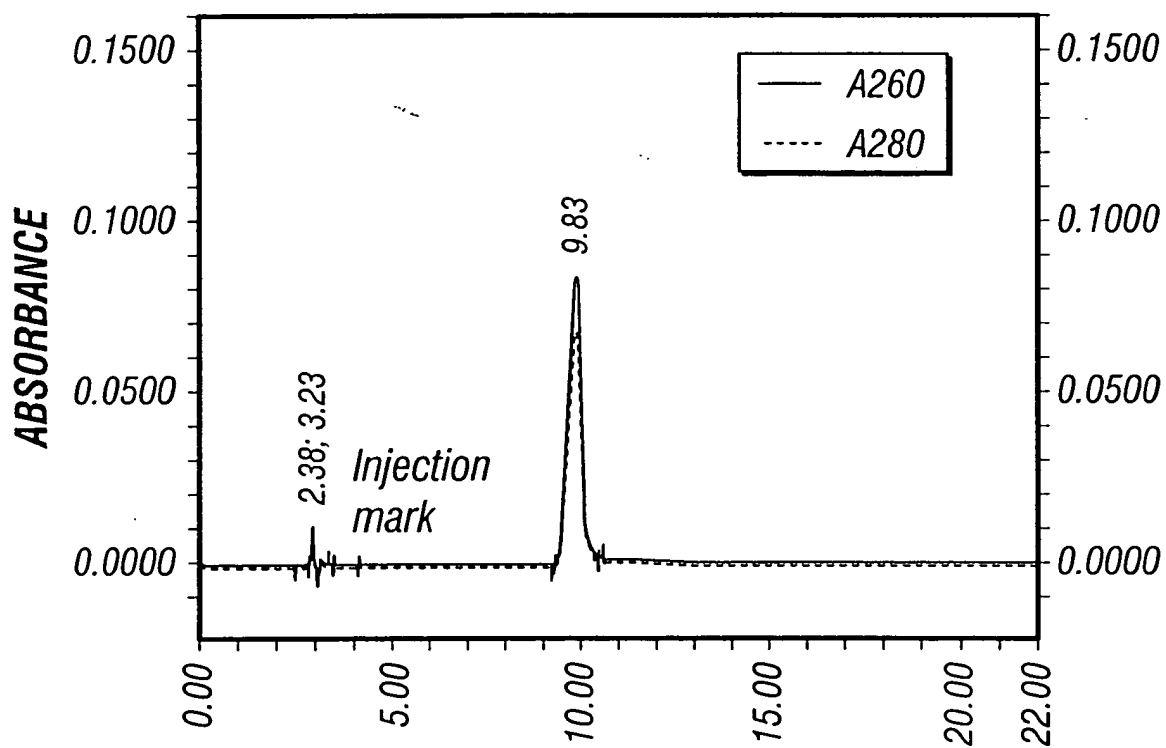


FIG. 26

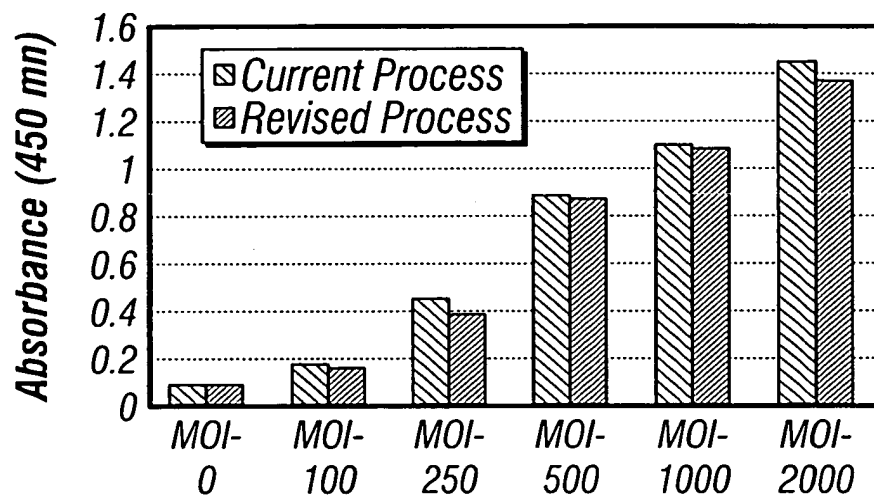


FIG. 27A

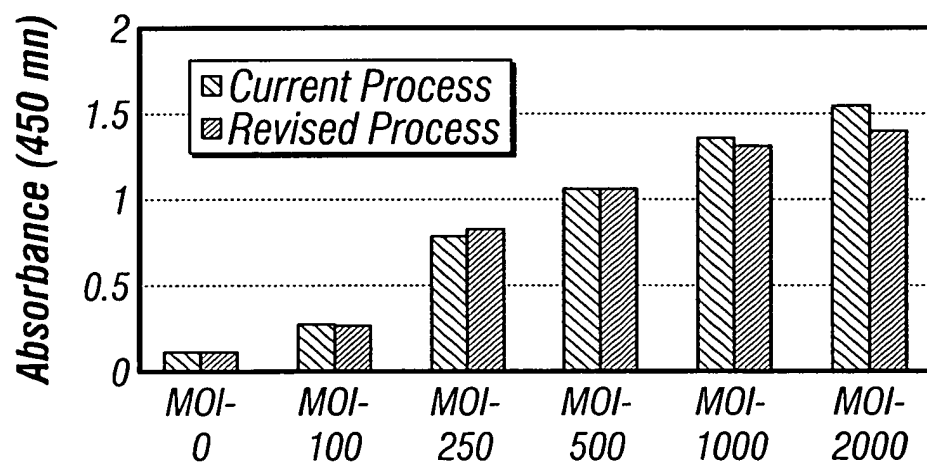


FIG. 27B

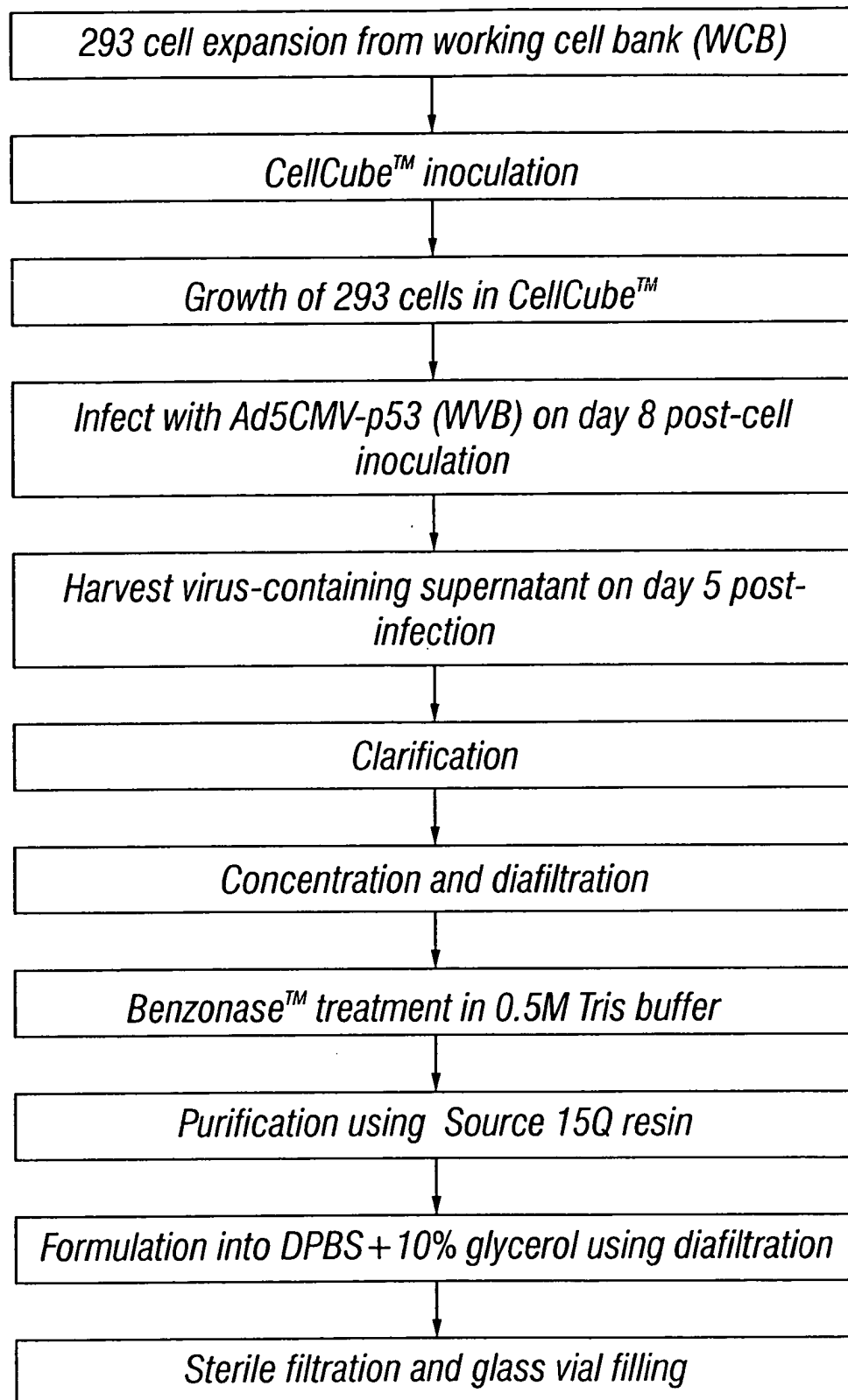


FIG. 28

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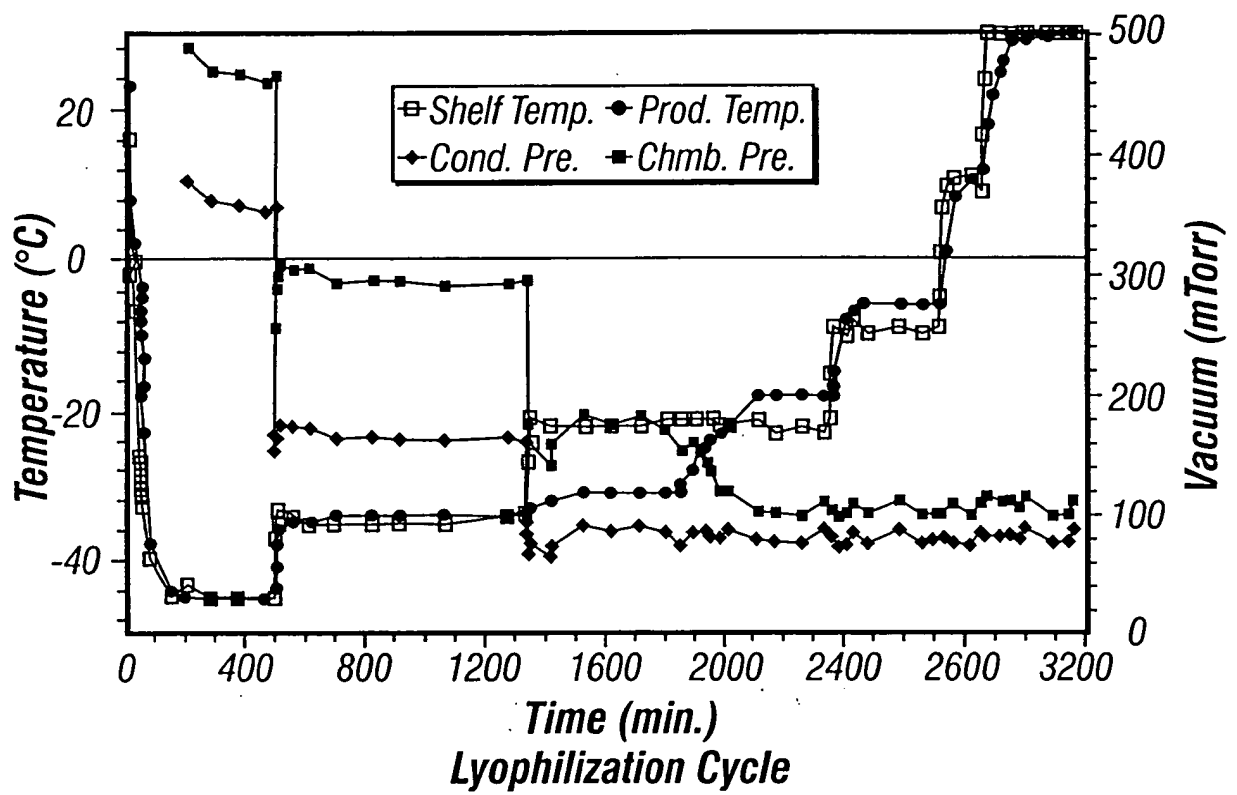


FIG. 29

Date (Temp.)	PFU x 10 <sup>9</sup> /ml				HPLC viral particles (x10 <sup>10</sup> )/ml				Water Content (W%)			
	SET 10-6	SET 10-7	SET 10-8	SET 10-9	SET 10-6	SET 10-7	SET 10-8	SET 10-9	SET 10-6	SET 10-7	SET 10-8	SET 10-9
4/11/97	5.5	6	5.8	6.5	24.5	24.6	24.9	26.7	2.2	2.5	2.7	3.3
5/15/97 (-20°C)	7.6	7.1	7.5	8.1	22.4	25.6	26.8	28.5	2.2	2.5	2.8	3.3
5/15/97 (4°C)	6.5	6.3	6.5	10	22	23	24	27.5	2.4	2.6	3	3.4
5/15/96 (R.T.)	7.1	7.1	6.7	3.3	14.5	16.5	6.2	4.2	2.7	2.9	3.2	3.5
7/18/97 (-20°C)	6.8	6.4	6.8	7.2	28.7	28.9	28.6	31.2	2.3	2.5	2.8	3.3
7/18/97 (4°C)	6	5.8	7.3	9	25	26.6	27.6	31.1	2.5	2.8	3	3.6
7/18/97 (R.T.)	1.2	0.8	4	1.4	0.9	1.8	0.7	0.7	2.7	2.9	3	3.4
10/22/97 (-20°C)	7.9	7.5	7.9	7.8	25.5	25	25.4	26.2	2.4	2.6	2.8	3.1
10/22/97 (4°C)	6.8	6.8	5.8	8	22	23	24.7	24.2	2.7	2.9	3.2	3.6
10/22/97 (R.T)	<0.01	<0.01	<0.01	<0.01	N.D.	N.D.	N.D.	N.D.	2.7	2.9	3.1	3.4
4/16/98 (-20°C)	6	5.8	7.1	7.2	19.3	20.3	23.5	26.1	2.4	2.6	3	3.4
4/16/98 (4°C)	5.4	7.2	6.1	6.3	21.7	22.8	22.9	24.6	2.9	3.1	3.3	3.8
4/16/98 (R.T.)	0.0003	0.001	0.0007	0.001	N.D.	N.D.	N.D.	N.D.	2.7	2.9	3.1	3.4

N.D.: Not detectable

FIG. 30A-1

## CONTROLS

Date	PFU x 10 <sup>9</sup> /ml				HPLC viral particles (x10 <sup>10</sup> )/ml			
	SET 10-6	SET 10-7	SET 10-8	SET 10-9	SET 10-6	SET 10-7	SET 10-8	SET 10-9
4/11/97	5.5	7	7	7	35.5	35.8	36	36.9

FIG. 30A-2

Date (Temp.)	PFU x 10 <sup>9</sup> /ml				HPLC viral particles (x10 <sup>10</sup> )/ml				Water Content (W%)			
	SET 11-6	SET 11-7	SET 11-8	SET 11-9	SET 11-6	SET 11-7	SET 11-8	SET 11-9	SET 11-6	SET 11-7	SET 11-8	SET 11-9
5/2/97	7	6	6.3	5.8	28.5	28.8	28.4	29.5	2.3	2.7	3.5	4
6/20/97 (-20°C)	6.2	6.6	6.9	6.5	26.3	25	27	27.3	2.2	2.8	3.4	4.6
6/20/97 (4°C)	6.1	6	6.5	6.5	24.1	22.1	25.6	26.6	2.5	2.8	3.5	4.8
6/20/97 (R.T.)	3.3	3	1	<0.1	20.5	17.4	5.2	9.1	2.7	3.1	3.5	4.7
8/18/97 (-20°C)	8	7.2	7.5	7.6	21.6	21.8	25.3	24.9	2.3	2.8	3.7	4.9
8/18/97 (4°C)	8	7.3	8	8	22.7	22.7	24.9	25	2.6	3	3.9	4.2
8/18/97 (R.T.)	<0.1	<0.1	<0.1	<0.1	N.D.	N.D.	0.2	13.1	2.7	3	3.5	4.4
10/22/97 (-20°C)	7.9	7.5	7.9	6.7	21	22	25.1	24	2.4	3	3.9	4.4
10/22/97 (4°C)	6	6.9	6.8	7.3	21.4	22	23.1	23.1	2.6	3	3.3	4.6
10/22/97 (R.T.)	<0.01	<0.01	<0.01	<0.01	N.D.	N.D.	N.D.	9	2.7	2.9	3.9	5
5/8/98 (-20°C)	8.3	7.5	8	8.7	19	18.2	19.9	21.1	2.6	3.1	4	4.6
5/8/98 (4°C)	7	7.1	7.8	6.5	17.3	17.1	18.2	17.8	2.8	3.2	4.1	5.1
5/8/97 (R.T.)	0.00033	0.000065	0.00045	0.000016	N.D.	N.D.	N.D.	N.D.	2.7	2.9	4	4.9

N.D.: Not detectable

FIG. 30B-1

## CONTROLS

CONTROLS							
Date	PFU x 10 <sup>9</sup> /ml				HPLC viral particles (x10 <sup>10</sup> )/ml		
	SET 11-6	SET 11-7	SET 11-8	SET 11-9	SET 11-6	SET 11-7	SET 11-8 SET 11-9
5/2/97	6.4	6.8	6.5	6.5	37.7	36.7	37.3 36

FIG. 30B-2



Date (Temp.)	PFU x 10 <sup>9</sup> /ml				HPLC viral particles (x10 <sup>10</sup> )/ml				Water Content (W%)			
	SET 10-6	SET 10-7	SET 10-8	SET 10-9	SET 10-6	SET 10-7	SET 10-8	SET 10-9	SET 10-6	SET 10-7	SET 10-8	SET 10-9
5/15/97	6.5	5.6	6.1	6	18	18.6	21.9	23.3	0.8	1.1	1.3	1.5
6/20/97 (4 °C)	5.4	5.6	5.5	5.5	14.6	14.9	17.2	16.6	0.8	1.2	1.5	1.6
6/20/97 (R.T.)	4.5	5	5.5	6	10.8	11.8	15	15.4	1.3	1.4	1.6	1.9
8/18/97 (4 °C)	7	6.7	6.8	7	15.3	17.1	17.9	17.7	1.3	1.5	1.5	1.7
8/18/97 (R.T.)	2.4	2.2	4.8	5.8	4.3	7.2	11.7	14.2	1.3	1.6	1.7	2.1
11/20/97 (4 °C)	5.5	5.5	5.3	5.7	16.8	16.8	20.6	20.1	1.1	1.4	1.6	1.9
11/20/97 (R.T.)	0.45	0.9	2.3	3.1	1.5	5.5	7.3	10.7	1.3	1.7	1.8	2.2
5/14/98 (4 °C)	4.9	4.7	5.4	6.5	9.7	11.9	12.6	14.2	1.2	1.6	2.2	1.4
5/14/98 (R.T.)	0.000006	0.00006	0.00004	0.000024	N.D.	N.D.	N.D.	N.D.	1.4	1.6	1.3	2

N.D.: Not detectable

FIG. 31A-1

## CONTROLS

Date	PFU x 10 <sup>9</sup> /ml				HPLC viral particles (x10 <sup>10</sup> )/ml			
	SET 10-6	SET 10-7	SET 10-8	SET 10-9	SET 10-6	SET 10-7	SET 10-8	SET 10-9
5/15/97	7	5.6	7	7	31.2	30.6	31.6	31.4

FIG. 31A-2

Date (Temp.)	PFU x 10 <sup>9</sup> /ml SET 11-6 SET 11-7 SET 11-8 SET 11-9				HPLC viral particles (x10 <sup>10</sup> )/ml SET 11-6 SET 11-7 SET 11-8 SET 11-9				Water Content (W%) SET 11-6 SET 11-7 SET 11-8 SET 11-9			
5/22/97	7.5	6.3	7.3	6.5	17.4	16.6	20.3	24.7	1	1.2	1.6	1.9
6/20/97 (4 °C)	5.5	6.3	6	7.5	14.8	16.1	17.5	21.1	1.2	1.3	1.7	1.8
6/20/97 (R.T.)	5	6	6	7.5	12.6	14.9	17.2	20.3	1.4	1.6	1.9	2
8/18/97 (4 °C)	6.3	6.7	6.8	7.5	15.7	17.2	18.5	22.6	1.2	1.5	1.8	1.9
8/18/97 (R.T.)	3.3	4.5	5.5	7	7.4	10.5	15.8	21.2	1.6	1.7	1.9	2.2
11/20/97 (4 °C)	5.3	5.6	5.3	6.6	17.3	20	22.6	26.3	1.2	1.4	1.9	1.9
11/20/97 (R.T.)	0.8	1.9	3	0.2	3.2	7.9	14.2	1.3	1.6	1.7	2	2.1
5/14/98 (4 °C)	6.7	7.2	6.9	7.6	12.4	13.9	15.5	18.5	1.3	1.6	2	2.2
5/14/98 (R.T.)	0.0013	0.00005	0.00031	0.00045	N.D.	N.D.	N.D.	N.D.	1.6	1.8	1.6	2

N.D.: Not detectable

FIG. 31B-1

CONTROLS

Date	PFU x 10 <sup>9</sup> /ml SET 11-6 SET 11-7 SET 11-8 SET 11-9				HPLC viral particles (x10 <sup>10</sup> )/ml SET 11-6 SET 11-7 SET 11-8 SET 11-9			
5/22/97	8	7.4	8.3	7.6	26.7	27.6	27.5	32.4

FIG. 31B-2

Date (Temp.)	PFU x 10 <sup>9</sup> /ml				HPLC viral particles (x10 <sup>10</sup> )/ml				Water Content (W%)			
	SET 10-6	SET 10-7	SET 10-8	SET 10-9	SET 10-6	SET 10-7	SET 10-8	SET 10-9	SET 10-6	SET 10-7	SET 10-8	SET 10-9
6/13/97	3.4	4.3	4.1	4.2	16	16.5	16.1	18.1	0.8	1.1	1.3	1.4
7/18/97 (4 °C)	6.3	6.3	6	6	17.9	19.5	19.9	20.6	0.9	1.2	1.4	1.6
7/18/97 (R.T.)	4.1	5.5	5	5.5	11.4	15.5	18.2	20.6	1.2	1.4	1.7	1.8
9/16/97 (4 °C)	4.2	5.5	4.5	5.1	15.3	16.1	16.4	17.8	1	1.3	1.5	1.7
9/16/97 (R.T.)	0.7	1.2	5	4	2.9	5	9.5	13	1.3	1.5	1.8	2
12/4/97 (4 °C)	5.5	5.3	5.4	5.9	16.1	16.2	18.1	18.5	1.1	1.4	1.6	1.7
12/4/97 (R.T.)	0.3	0.5	2.5	3.4	N.D.	1.7	4.7	8.8	1.4	1.6	1.8	2
6/29/98 (4 °C)	3.8	5.1	5.3	5.4	10.6	10.8	12	12.9	1.3	1.5	1.8	1.9
6/29/98 (R.T.)	0.00003	0.00006	0.0001	0.0001	N.D.	N.D.	N.D.	N.D.	1.4	1.6	1.7	1.8

N.D.: Not detectable

FIG. 32A-1

CONTROLS

Date	PFU x 10 <sup>9</sup> /ml				HPLC viral particles (x10 <sup>10</sup> )/ml			
	SET 10-6	SET 10-7	SET 10-8	SET 10-9	SET 10-6	SET 10-7	SET 10-8	SET 10-9
6/13/97	4.7	3.8	5.5	6.2	26	26.2	27.4	27.5

FIG. 32A-2

Date (Temp.)	PFU x 10 <sup>9</sup> /ml				HPLC viral particles (x10 <sup>10</sup> )/ml				Water Content (W%)			
	SET 11-6	SET 11-7	SET 11-8	SET 11-9	SET 11-6	SET 11-7	SET 11-8	SET 11-9	SET 11-6	SET 11-7	SET 11-8	SET 11-9
6/13/97	3.4	4.2	3.6	4.4	16.1	16.3	18.4	19.3	0.9	1.3	1.8	1.9
7/18/97 (4 °C)	5.5	6.2	6.5	6.2	18	19.5	23	23.9	1	1.4	1.8	2.1
7/18/97 (R.T.)	3.7	6	6.7	7.3	13.7	18.7	21.8	22.8	1.3	1.7	2	2.2
9/16/97 (4 °C)	3.9	4	4.6	6	15.6	17.3	19.5	20.6	1.3	1.5	1.9	2.1
9/16/97 (R.T.)	0.8	2.2	4	5.3	3.6	6.8	13.8	14.6	1.5	1.9	2.3	2.4
12/4/97 (4 °C)	4.6	5.3	8	6.1	15.7	18.2	21.4	21.6	1.2	1.6	2.1	2.2
12/4/97 (R.T.)	0.4	0.6	0.3	<0.01	N.D.	N.D.	1.7	N.D	1.6	1.8	2.1	2.1
6/29/98 (4 °C)	4.9	5	5.4	6.4	11.4	14.2	13.7	16	1.5	1.7	2.1	2.6
6/29/98 (R.T.)	0.0001	0.00015	0.00085	0.0012	N.D.	N.D.	N.D.	N.D.	1.6	1.7	2.2	2.3

N.D.: Not detectable

FIG. 32B-1

CONTROLS

Date	PFU x 10 <sup>9</sup> /ml				HPLC viral particles (x10 <sup>10</sup> )/ml			
	SET 11-6	SET 11-7	SET 11-8	SET 11-9	SET 11-6	SET 11-7	SET 11-8	SET 11-9
6/13/97	4.5	5	4	5	26.5	26.9	26.6	27.1

FIG. 32B-2

Date (Storage Cond.)	PFU x 10 <sup>9</sup> /ml				HPCL viral particles (x10 <sup>10</sup> )/ml			
	10%-G	5%-s,5%-HSA	5%-S, %-PEG	5%-T,1%-PEG	10%-G	5%-s,5%-HSA	5%-S, %-PEG	5%-T,1%-PEG
8/1/97	5.8	4.7	4.3	4.4	16.9	14.5	16.1	16.7
8/28/97 (4°C, N <sub>2</sub> )	5.8	5.8	6.4	6.3	13.3	14.9	13.8	13.4
8/28/97 (4°C, AIR)	5	5.9	6	5.9	12.9	14.2	12.9	12.9
8/28/97 (R.T., N <sub>2</sub> )	4.4	4.8	5	6	12.6	14.5	13.5	12.9
8/28/97 (R.T., AIR)	4.3	5	5	5.6	12.3	13.7	13	13
10/30/97 (4°C, N <sub>2</sub> )	3.8	4	4.7	3.8	14	15.5	14.7	14.8
10/30/97 (4°C, AIR)	3	4.1	3.7	4.7	12.6	14.9	14.3	14.4
10/30/97 (R.T., N <sub>2</sub> )	1.5	3.4	3.5	3.6	13.8	15.1	14.6	14.4
10/30/97 (R.T., AIR)	1.5	3.6	2.2	3.1	12.7	14.7	14.8	14.4
1/12/98 (4°C, N <sub>2</sub> )	3.2	4.1	3.3	3.4	7.3	11.1	9.5	9.5
1/12/98 (4°C, AIR)	1.5	3.8	3.9	3.4	7.7	10.8	10.2	10
1/12/98 (R.T., N <sub>2</sub> )	0.1	1.4	0.7	0.7	10	10.8	11.1	10.4
1/12/98 (R.T., AIR)	0.4	1.6	1	0.4	9.9	11	10	10.4
4/30/98 (4°C, N <sub>2</sub> )	0.08	4.3	4	5.3	5.1	12.3	12.3	12.1
4/30/98 (4°C, AIR)	1.5	3.6	4.4	4.5	5	11.6	11.8	11.9
4/30/98 (R.T., N <sub>2</sub> )	0.0025	0.23	0.11	0.17	11.1	12.3	12.6	12.5
4/30/98 (R.T., AIR)	0.0015	0.21	0.063	0.007	11	12.4	12.3	11

FIG. 33

Date (Temp.)	PFU x 10 <sup>9</sup> /ml											
	AQF2-1	AQF2-2	AQF2-3	AQF2-4	AQF2-5	AQF2-6	AQF2-7	AQF2-8	AQF2-9	AQF2-10	AQF2-11	AQF2-12
9/25/97	2.8	2.8	2.8	3	2.8	2.8	2.7	2.8	2.7	3.3	3.1	2.7
11/05/97 (4°C)	2.3	3.2	2.4	3.6	2.7	2	3.6	3.8	2.7	3	3.5	2.5
11/05/97 (R.T.)	2.2	0.1	2.4	2.7	2.1	2.1	3.2	2.1	3	3	3.4	2.9
12/12/97 (4°C)	2.2	0.1	2.4	2.7	2.1	2.1	3.2	2.1	3	3	3.4	2.9
01/09/98 (R.T.)	1.2	<0.1	0.2	1.2	0.2	0.1	1.3	1.1	0.2	<0.1	2	1.1
3/27/98 (4°C)	1.8	<0.1	1.9	2	<0.1	1.7	2	<0.1	2.6	2.9	2.6	1.8
3/27/98 (R.T.)	0.6	<0.1	<0.1	0.8	<0.1	<0.1	1	<0.1	<0.1	<0.1	1.1	0.7

FIG. 34A-1

Date (Temp.)	HPLC viral particles (x10 <sup>10</sup> /ml)											
	AQF2-1	AQF2-2	AQF2-3	AQF2-4	AQF2-5	AQF2-6	AQF2-7	AQF2-8	AQF2-9	AQF2-10	AQF2-11	AQF2-12
9/25/97	10.9	9.6	9.7	11.3	10.7	10.6	10.9	10.8	10.7	11.4	11.8	10.7
11/05/97 (4°C)	7.9	7.6	8.7	8.8	8.9	7.5	8.6	9.1	9.2	10.3	11.2	9.6
11/05/97 (R.T.)	8.2	6.6	7.6	8.6	7.7	9.3	9	8	9.3	10.3	11.1	9.6
12/12/97 (4°C)	6.7	1.5	8	6.9	5.2	7.5	7.5	6.1	7.6	8.8	7.3	7.7
12/17/98 (R.T.)	7	1.2	7	7.5	4.1	7.1	7	3	8.2	7.6	8.4	7.5
3/13/98 (4°C)	5.6	N.D.	6.2	6.7	N.D.	6.5	6.8	N.D.	7.1	8	8.9	7.2
3/13/98 (R.T.)	6.2	N.D.	6.5	6.9	N.D.	7.3	6.8	N.D.	6.9	7.8	7.5	7.1

FIG. 34A-2

Excipients	AQF2-1	AQF2-2	AQF2-3	AQF2-4	AQF2-5	AQF2-6	AQF2-7	AQF2-8	AQF2-9	AQF2-10	AQF2-11	AQF2-12
Mannitol (W%)	5	5	5				5	5	5	5	5	
Sucrose (W%)				5	5	5	5	5	5	5	5	10
Glycine (M)	0.25			0.25			0.25				0.25	0.25
Arginine (M)		0.25			0.25			0.25			0.25	
Urea (W%)			1			1			1		1	
Peg (W%)										1	1	

FIG. 34B

<i>Date (Temp.)</i>	<i>PFU x 10<sup>9</sup></i>				<i>HPLC viral particles(x 10<sup>10</sup>/ml)</i>			
	<i>F10-7</i>	<i>F10-8</i>	<i>F11-7</i>	<i>F11-8</i>	<i>F10-7</i>	<i>F10-8</i>	<i>F11-7</i>	<i>F11-8</i>
10/3/97	2.2	3.3	2.1	2.8	12.1	12	11.8	12
11/6/97 (-20°C)	3.4	4	2.8	3.4	10.6	10.5	10.1	10.3
11/6/97 (4°C)	3.5	3.6	4.3	2.8	10	9.7	9.9	10.3
1/15/98 (-20°C)	3.8	4.8	3.2	3.7	7.3	7.4	7.7	8
1/15/98 (4°C)	3.5	3.1	2.9	3.1	7.5	7.4	7.6	7.5

FIG. 35-1

<i>Excipients</i>	<i>F10-7</i>	<i>F10-8</i>	<i>F11-7</i>	<i>F11-8</i>
<i>Mannitol (W%)</i>	6	6	5	5
<i>Sucrose (W%)</i>	7	8	7	8
<i>HSA (W%)</i>	0.5	0.5	0.5	0.5
<i>Glycerol (W%)</i>	1	1	1	1
<i>MgCl<sub>2</sub> (mM)</i>	1	1	1	1

FIG. 35-2

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Date (Temp.)	PFU x 10 <sup>9</sup>						
	AQF4-1	AQF4-2	AQF4-3	AQF4-4	AQF4-5	AQF4-6	AQF4-7
1/13/98	3	2.5	3.6	3.4	2.7	3.1	3.4
2/11/98 (4°C)	2.5	3.2	3.3	2.9	2.6	2.9	2.6
2/11/98 (R.T.)	1.8	2.7	1.6	3.6	2.6	1.6	1.7
4/10/98 (4°C)	2.2	2	2.6	3	2.4	1.9	2.2
4/10/98 (R.T.)	0.4	0.4	0.3	0.5	0.4	<0.1	1.1
7/24/98 (4°C)	2.4	2.8	2.6	3.5	1.9	2.2	2.6
7/24/98 (R.T.)	0.002	0.005	0.006	0.005	0.005	0.005	0.001

FIG. 36-1

Date (Temp.)	HPCL Intergrated Area						
	AQF4-1	AQF4-2	AQF4-3	AQF4-4	AQF4-5	AQF4-6	AQF4-7
1/13/98	8.7	10.9	11.5	11.1	9.5	9.7	11.3
2/16/98 (4°C)	9.1	9.3	9.2	9.5	8.2	8.4	9.6
2/16/98 (R.T.)	6.8	9	9.5	9	8.7	8.4	9.3
4/10/98 (4°C)	7.1	9.2	9.6	9.6	8.9	9.1	9.9
4/10/98 (R.T.)	7.5	9.5	10.1	9.7	8.9	8.9	9.5
7/24/98 (4°C)	8.1	9.9	11.1	10.3	9.2	7.4	9.3
7/24/98 (R.T.)	7.3	3	10.7	8.9	10.4	10.45	3.5

FIG. 36-2

Excipients	AQF4-1	AQF4-2	AQF4-3	AQF4-4	AQF4-5	AQF4-6	AQF4-7
Mannitol (W%)	5	5	5	5	5	5	5
Sucrose (W%)	5	5	5	5	5	5	5
Tween 80 (W%)		0.02	0.1	0.5			
Chap (W%)					0.02	0.1	0.5

FIG. 36-3

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